NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

March 4-5, 2026

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

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

Please do not remove the book from the meeting room.

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

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

Date Posted: February 23, 2026

SECOND AMENDED AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, March 4, 2026, at 9:00 am. The meeting will continue Thursday, March 5, 2026, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

3. Approval of the January 14-15, 2026, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

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

   A. CloudCath – San Francisco, CA
   B. Geodis Logistics LLC – Plainfield, IN
   C. Intouch Med Supply Co – King of Prussia, PA
   D. Medline Industries – Perryville, MD
   E. SleepSafe Drivers Inc – Lenexa, KS
   F. Unicare Diagnostics LLC – Newbury Park, CA

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

   Background Check Not Required by Law.

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

   G. Cogent Biosciences Inc – Waltham, MA
   H. MIMEDX Group Inc – Marietta, GA

I. McKesson Medical-Surgical Inc – Kansas City, MO
J. NuSmile Ltd – Houston, TX

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

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

K. Ethicon Endo-Surgery Inc – Cincinnati, OH
L. Stryker Spine LLC – Allendale, NJ
M. Stryker Sustainability Solutions Inc – Tempe, AZ
N. Viridian Therapeutics Inc – Waltham, MA

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

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

O. J & B Medical Supply Co. Inc – Wixom, MI
P. Optime Care Inc – Earth City, MO
Q. Teleflex LLC – Chelmsford, MA
R. Teleflex LLC – Olive Branch, MS

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

S. Abrasive Technology LLC – Lewis Center, OH
T. Aiping Pharmaceutical Inc – Hauppauge, NY
U. Arvato USA LLC – Memphis, TN
V. Ascent Pharmaceuticals Inc – Central Islip, NY
W. Blueprint Medicines Corporation – Cambridge, MA
X. B. Braun Medical Inc – Carrollton, TX
Y. Ceva Animal Health LLC – Lenexa, KS
Z. K2M Inc – Leesburg, VA
AA. LifeScience Logistics LLC – Memphis, TN
BB. Novartis Manufacturing LLC – Carlsbad, CA
CC. Philips Image Guided Therapy Corporation – San Diego, CA
DD. Renaissance Lakewood LLC – Lakewood, NJ
EE. Reliable Healthcare Logistics LLC – Boca Raton, FL
FF. Reliable Healthcare Logistics LLC – Dayton, NJ
GG. Reliable Healthcare Logistics LLC – Lockbourne, OH
HH. Reliable Healthcare Logistics LLC – Pompano Beach, FL
II. Reliable Healthcare Logistics LLC – Sugarland, TX

JJ. Trilliant Surgical LLC – Houston, TX
KK. Visus Therapeutics Inc – Beavercreek, OH

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

LL. Coupler LLC – West Chester, PA

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

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

MM. A2A Alliance Pharmaceuticals LLC – Franklin, KY
NN. FedEx Supply Chain Inc – Indianapolis, IN
OO. Schraders Medical Supply Inc – Montclair, CA

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

PP. Spring Mountain Sahara an extension of Spring Valley Hospital – Las Vegas, NV

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

QQ. Chartwell Pennsylvania LP – Oakdale, PA
RR. Hartley Medical Center Pharmacy – Long Beach, CA
SS. Lake Hills Pharmacy – Austin, TX
TT. Logos Pharmacy – Tampa, FL
UU. Pharmacorr Sterile LLC – Oklahoma City, OK
VV. PharmaLogic Los Angeles – Los Angeles, CA
WW. Source Pharmacy – West Palm Beach, FL

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

XX. Affordable Script – Valley Stream, NY
YY. Almac Clinical Services LLC – Durham, NC
ZZ. Brightside Specialty Pharmacy – Santa Ana. CA
AAA. City Drug – Evanston, WY
BBB. Formulate Rx Pharmacy – Winter Springs, FL
CCC. Gifthealth Pharmacy AZ – Mesa, AZ
DDD. Honeybee Health – Culver City, CA

EEE. InfuCare Rx of MD – Cumberland, MD
FFF. InfuCare Rx of NJ – Pine Brook, NJ
GGG. Innovarx Inc – Morganville, NJ
HHH. Magic City Pharmacy – Pelham, AL
III. Optime Care Inc – Earth City, MO
JJJ. Pharma Fusion LLC – Bullhead City, AZ
KKK. Santa Rosa Pharmacy – Santa Rosa Beach, FL

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

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

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

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

◈ REGULAR AGENDA ◈

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

A. Matthew Apel	(24-044-PD-A-S)
B. Thomas Umbach	(24-044-PD-B-S)
C. Susan Nytes	(24-213-CS-S)
D. Ivan Goldsmith	(24-488-CS-S)
E. SouthwestDME	(25-143-MP-S)
F. Marika Kerr	(25-146-CS-S)
G. Festus Ebonka	(25-215-CS-S)
H. CVS Pharmacy #8822	(23-051-PH-S)
I. Ryan Clements	(23-051-RPH-S)
J. PharMerica	(24-370-PH-N)
K. Camilla Kim	(24-370-RPH-N)
L. Amy Tseng	(24-484-CS-S)
M. CVS Pharmacy #6717	(24-013-PH-S)
N. Analeah Presbitero	(24-013-RPH-A-S)
O. Todd Spears	(24-013-RPH-B-S)
P. Michael Stellmacher	(24-364-CS-S)
Q. First Choice Pharmacy	(25-110-PH-S)
R. Nicole Sy	(25-110-RPH-A-S)
S. Kirk Beaulieu	(25-110-RPH-B-S)
T. Jill Allison Oliver	(25-111-CS-S)
U. Lyfe Pharmacy	(25-360-PH-S)

V. Nazokat Nigmatova (25-360-RPH-S)
W. Tera Pharmacy (25-370-PH-S)
X. Nazokat Nigmatova (25-370-RPH-A-S)
Y. Grace Singson (25-370-RPH-B-S)

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

A. Carolina Molina (25-146-S)
B. Prime Plus Lakeview Pharmacy (25-110-V-O)
C. Oxus America, Inc (25-470-O)

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

A. ActivStyle, LLC – Las Vegas, NV
B. Dia-Foot – Las Vegas, NV
C. The Re-Habit Wellness Castle – Las Vegas, NV

8. Applications for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

A. Arise Pharmacy – Las Vegas, NV
B. Capital Care Pharmacy – Las Vegas, NV
C. Community Reach Pharmacy – Las Vegas, NV
D. Lyfe Pharmacy – Las Vegas, NV
E. Nevada Care Pharmacy – Las Vegas, NV
F. QHR Pharmacy – Las Vegas, NV
G. Tera Pharmacy – Las Vegas, NV

9. Application for Nevada Outsourcing Facility (NRS 639.100) – Appearance (**FOR POSSIBLE ACTION**)

A. Orion Specialty Labs, LLC – Henderson, NV

10. Applications for Nevada Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLLE ACTION)**

A. CAD-Ray Distribution, Inc – Las Vegas, NV - Background Check Not Required by Law
B. Dia-Foot – Las Vegas, NV - Background Check Not Required by Law
C. Stryker Orthopaedics – Las Vegas, NV - Background Check Not Required by Law
D. Stryker Orthopaedics – Reno, NV - Background Check Not Required by Law

11. Application for Pharmacist Registration by Reciprocation NRS 639.134) – Appearance (**FOR POSSIBLE ACTION**)

A. Paul Arp

12. Application for Pharmaceutical Technician Registration (NAC 639.240) – Appearance. (**FOR POSSIBLE ACTION)**

A. Crystal Lara

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

A. Hisbay Ali
B. Michael Roach
C. Orlandis Wells

14. Discussion on Audit by Casey Neilon Pursuant to NRS 218G.400 for Fiscal Year Ending June 30, 2025 – **(FOR POSSIBLE ACTION)**

◈ WORKSHOP ◈

Thursday, March 5, 2026 – 9:00 am

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

A. Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding N-pyrrolidino metonitazene and N-pyrrolidino protonitazene to the controlled substances listed in Schedule I.

◈ PUBLIC HEARING ◈

Thursday, March 5, 2026 – 9:00 am

16. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION)**

A. A REGULATION relating to controlled substances adding dipentylone and seven fentanyl related substances to the controlled substances listed in Schedule I; and providing other matters properly relating thereto. (LCB File No. R107-25)

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

18. Executive Secretary Report:

A. Financial Report

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

19. Date and Location of Next Scheduled Board Meeting:

April 15-16, 2026 – Reno, NV

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

21. Adjournment

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

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

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

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

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NEVADA STATE BOARD OF PHARMACY

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

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

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

BOARD MEETING MINUTES

January 14-15, 2026

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, January 14, 2026, at 9:00 am. The meeting will continue Thursday, January 15, 2026, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Board Members Present:

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

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Brett Kandt
Laura Tucker	Skylar Young	Todd Weiss	Darlene Nases
Erin Miller	Joe Dodge	Leo Basch	Jessette Phaynarikone
John Castaldo	Darla Zarley	Dena McClish	Ken Scheuber
William Kuykendall	Michael Castaneda	Clayton Bailey	

Call to Order and Roll Call – Establishment of Quorum

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

DRAFT

Public Comment at January 14, 2026, 9:04 AM

There was no public comment.

1. Approval of December 3-4, 2025, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board Action:

Motion: Jade Jacobo moved to approve the December 3-4, 2025, Board Meeting Minutes.

Second: Adam Porath

Action: Passed unanimously.

◈ CONSENT AGENDA ◈

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

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

A. HealthRom Inc – Brookfield, CT
B. Livefree Medical, LLC – Awendaw, SC
C. Schrader's Medical Supply – Montclair, CA
D. United States Medical Supply, LLC – Doral, FL

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

Background Check Not Required by Law.

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

E. Henry Schein Marketplace – West Columbia, SC

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

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

F. Achieve Life Sciences, Inc – Bothell, WA

G. Abeona Therapeutics, Inc – Cleveland, OH
H. Cinqualate Therapeutics, LLC – Westwood, KS
I. Disc Medicine, Inc – Watertown, MA
J. Revolution Medicines, Inc – Redwood City, CA

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

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

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

K. Bora Pharmaceuticals, Inc – Maple Grove, MN
L. Cordis US Corp – Santa Clara, CA
M. Direct Rx – Dawsonville, GA
N. Esjay Pharma LLC – East Winsor, NJ
O. Med-Vet International – Mettawa, IL
P. Renova Pharmaceuticals, LLC – Fairfield, NJ

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

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

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

Q. Chewy Wholesale MCO5, LLC – Ocala, FL
R. FedEx Supply Chain, Inc – York, PA
S. Geodis Logistics, LLC – Clayton, IN
T. Guardian DME LLC – Las Vegas, NV
U. Kuehne + Nagel, Inc – Shelbyville, KY
V. Logical Pharma Solutions – Phoenix, AZ
W. Resource Optimization & Innovation, LLC – Earth City, MO
X. ReviveMed Pharmaceuticals, LLC – Denver, CO
Y. R & S Northeast LLC – Glasgow, KY
Z. VaxServe, Inc – Moosic, PA

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

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

DRAFT

AA. Affirming Care Pharmacy – San Antonio, TX
BB. Biologics by McKesson – Shepherdsville, KY
CC. Cache Valley Pharmacy – North Logan, UT
DD. EPSRX – Farmers Branch, TX
EE. FarmaKeio AR – Conway, AR
FF. Good Day Pharmacy – Johnstown, CO
GG. Medivera Compounding Pharmacy – Troy, MI
HH. Safeway Pharmacy #1474 – Ft. Mohave, AZ
II. Smithville Pharmacy – Smithville, TX
JJ. Stellus Rx #1001 – Plano, TX
KK. TelyRX Dallas, LLC – Irving, TX
LL. Walmart Central Fill #10-2489 – Litchfield Park, AZ

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

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

MM. Nevada Heart and Vascular Optum Surgery Center – Las Vegas, NV

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

NN. Francisca Evangelista
OO. Joanne Dominguez

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

4.9 Application for Out-of-State Outsourcing Facility (NRS 639.100) – Non-Appearance (**FOR POSSIBLE ACTION**)

PP. STAQ Pharma of Ohio, LLC – Columbus, OH

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda.

Second: Chanyis Taylor

Action: Passed unanimously.

◈ REGULAR AGENDA ◈

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

AA. Walgreens Pharmacy #03842 (24-451-PH-S)

William Stilling, Esq., was present on behalf of Walgreens Pharmacy #03842.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Walgreens Pharmacy #03842 alleging that as the pharmacy/pharmacy owner, Walgreen's Pharmacy #03842 is responsible for the acts of its employees who made an error in a prescription that resulted in a negative outcome to the patient.

The proposed stipulated penalties for Walgreens Pharmacy #03842, License No. PH01249, are the following: 1) Respondent fined $1,000 for the violations; 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable within thirty (30) days of the effective date of the Order; 3) Respondent will ensure that all pharmacies in Nevada that use automated filling cells require pharmacists to review the SOPs for filling automated cells with medications from stock bottle and will provide documentation to Board staff within sixty (60) days of the effective date of the Order; and 4) Respondent will cease using the Yuyama EV-1 automated filling cells as of January 31, 2026.

Ms. Tucker requested to amend paragraph 8, section D of the Order to read "January 31, 2026" instead of "January 31, 2025", as well as paragraph 10 to read "January 14, 2026" instead of "December 3, 2025".

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Walgreens Pharmacy #03842, with the amendments requested, as presented by Ms. Tucker.

Second: Jade Jacobo

Action: Passed unanimously.

N. David Whitehouse (23-429-RPH-B-S)

David Whitehouse was present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Mr. Whitehouse, alleging that, as managing pharmacist during the time of the events, Respondent Whitehouse is responsible for the acts of its employees at Partell Pharmacy who dispensed invalid “Emergency Kits” or “COVID Kits” for which the drugs in each kit were not identified on the prescription, and they would substitute Budesonide in the “COVID Kit” with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner.

The proposed stipulated penalties for David Whitehouse, Certificate of Registration No. 13635, are the following: 1) Respondent’s Certificate of Registration No. 13635 has been forfeited because Respondent failed to renew it; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney’s fees and costs, both to be due and payable on or before February 28, 2026.

Mr. Zunino requested to amend paragraph 8, section D of the Order to read “February 28, 2026” instead of “February 28, 2025”.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for David Whitehouse, with the amendment requested, as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously.

A.	CVS Pharmacy #8824	(22-509-PH-S)
B.	Karlo Arceo	(22-509-RPH-S)

Jade Jacobo recused herself from this matter due to her previous employment with CVS.

President Park disclosed that she was familiar with Karlo Arceo from Roseman University, but she could participate in this matter fairly and without bias.

Karlo Arceo and Brian Convery (Representative for CVS Pharmacy #8824) were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against CVS Pharmacy #8824 alleging that as the pharmacy/pharmacy owner, CVS

Pharmacy #8824 is responsible for the acts of its employees who made an error in a prescription that resulted in negative outcome to the patient.

Mr. Kandt prosecuted the case against Karlo Arceo alleging that Respondent Arceo made an error in a prescription that resulted in negative outcome to the patient.

The proposed stipulated penalties for Karlo Arceo, Certificate of Registration No. 19697, are the following: Respondent's Certificate of Registration No. 19697 is suspended for a period of one (1) year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable by February 1, 2026.

The proposed stipulated penalties for CVS Pharmacy #8824, License No. PH00947, are the following: 1) Respondent fined $10,000 for the violations; and 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due by February 1, 2026.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Orders for CVS Pharmacy #8824 and Karlo Arceo as presented by Mr. Kandt.

Second: Adam Porath

Action: Motion passed (Jacobo recused).

C. Rodelyn Arceo (23-353-CS-S)

Michael M. Lin, Esq., was present on behalf of Rodelyn Arceo.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Rodelyn Arceo alleging that Respondent Arceo allowed non-practitioners to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.

The proposed stipulated penalties for Rodelyn Arceo, Certificate of Registration No. CS30228, are the following: Respondent's Certificate of Registration No. CS30228 is suspended for a period of one (1) year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $5,000 for the violations; and 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by July 3, 2026.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Rodelyn Arceo as presented by Mr. Kandt.

Second: Jade Jacobo

Action: Passed unanimously.

H. Gregory Allen Oliver (24-224-CS-S)

Gregory Allen Oliver was present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Gregory Allen Oliver alleging that Respondent Oliver dispensed controlled substances without a valid dispensing practitioner registration and failed to review the PMP.

The proposed stipulated penalties for Gregory Allen Oliver, Certificate of Registration No. CS35044, are the following: Respondent's Certificate of Registration No. CS35044 is suspended for a period of one (1) year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $5,000 for the violations; and 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by July 3, 2026.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Gregory Allen Oliver as presented by Mr. Kandt.

Second: Jade Jacobo

Action: Passed unanimously.

J. Costco Pharmacy #673 (24-462-PH-S)
K. Chi Vu (24-462-RPH-S)

Chi Vu and Andrew Joseph Liu (Regional Pharmacy Supervisor for Costco) were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Costco Pharmacy #673 alleging that as the pharmacy/pharmacy owner, Costco

Pharmacy #673 is responsible for the acts of its employees who made an error in a prescription.

Mr. Kandt prosecuted the case against Chi Vu alleging that Respondent Vu made an error in a prescription.

The proposed stipulated penalties for Chi Vu, Certificate of Registration No. 18811, are the following: 1) Respondent fined $1,000 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable by April 1, 2026.

The proposed stipulated penalties for Costco Pharmacy #673, Pharmacy License No. PH00825, are the following: 1) Respondent fined $2,000 for the violations; and 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by April 1, 2026.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Orders for Costco Pharmacy #673 and Chi Vu as presented by Mr. Kandt.

Second: Chanyis Taylor

Action: Passed unanimously.

L. Danny Young (24-498-CS-S)

Forrest Zimmerman, Esq., was present on behalf of Danny Young.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Danny Young alleging that Respondent Young allowed a non-practitioner to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.

The proposed stipulated penalties for Danny Young, Certificate of Registration No. CS06454, are the following: Respondent's Certificate of Registration No. CS06454 is placed on probation for a period of one (1) year, subject to the following conditions: 1) Respondent fined $5,000 for the violations; and 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by February 27, 2026.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Danny Young as presented by Mr. Kandt.

Second: Jade Jacobo

Action: Passed unanimously.

U. Robert Milne (23-418-CS-S)

Chris R. McCullough, Esq., was present on behalf of Robert Milne.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Robert Milne alleging that Respondent Milne dispensed dangerous drugs without a dispensing registration; held for sale an adulterated drug; failed to produce complete and accurate records of all dangerous drugs dispensed to patients; failed to store and/or possess dangerous drugs from patients and employees that were not in stock containers properly labeled and procured from a manufacturer, wholesaler or pharmacy; and did not acquire the dangerous drugs from patients and employees pursuant to a prescription written by himself or another practitioner, and/or were not dispensed to Respondent by a pharmacy or dispensing practitioner.

The proposed stipulated penalties for Robert Milne, Certificate of Registration No. CS03445, are the following: 1) Respondent fined $5,000 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, both to be due and payable within thirty (30) days of the effective date of the Order.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the Stipulation and Order for Robert Milne as presented by Ms. Tucker.

Second: Richard Tomasso

Action: Passed unanimously.

M. Aaron Webb (24-505-RPH-O)

Aaron Webb and Mark Armstrong (counsel) were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Aaron Webb for reciprocal disciplinary action on Certificate of Registration No. 22724 based upon disciplinary action by the Arizona Board of Pharmacy for diversion.

The proposed stipulated penalties for Aaron Webb, Certificate of Registration No. 22724, are the following: Respondent's Certificate of Registration No. 22724 is placed on probation until October 29, 2029, and subject to the following conditions: 1) Respondent must fully comply with the consent agreement with Arizona State Board of Pharmacy's Case No. 24-0394; and 2) Respondent fined $1,000 for the violations, due and payable by February 27, 2026.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Aaron Webb as presented by Mr. Kandt.

Second: Adam Porath

Action: Passed unanimously.

R. Saman Sazegar (25-420-RPH-S)

Saman Sazegar was present.

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

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Saman Sazegar alleging that Respondent Sazegar was arrested for a DUI and was under the influence of alcohol and Diazepam, a controlled substance. He did not have a valid U.S. prescription as he obtained the medication from a prescription issued by a licensed physician in Thailand. Respondent was disciplined by the California BOP.

Respondent Sazegar has fully satisfied the conditions imposed by the California State Board of Pharmacy.

The proposed stipulated penalties for Saman Sazegar, Certificate of Registration No. 20754, are the following: 1) Respondent accepts the Order as public reprimand for having possessed diazepam without a prescription and having violated federal law related to the importation of prescription drugs; and 2) Respondent assessed $500 in attorney's fees and costs, to be due and payable on or before February 28, 2026.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Saman

Sazegar, with the amendment to the date in the Decision and Order to read “2026” instead of “2025”, as presented by Mr. Zunino.

Second: Chanyis Taylor

Action: Passed unanimously.

S.	Sunrise Pharmacy	(20-097-PH-S)
T.	Tamara Angeles	(20-097-RPH-S)

Joey Gilbert, Esq., was present on behalf of Sunrise Pharmacy and Tamara Angeles.

President Park disclosed that she was familiar with Tamara Angeles from her time at Roseman University, but she could participate in this matter fairly and without bias.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Sunrise Pharmacy alleging that as the pharmacy/pharmacy owner, Sunrise Pharmacy is responsible for the acts of its employees who mailed dangerous drugs to California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail-order pharmacy license in those states.

Ms. Tucker prosecuted the case against Tamara Angeles, alleging that, as managing pharmacist during the time of the events, Respondent Angeles was aware and is responsible for the acts of its employees who mailed dangerous drugs to California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail-order pharmacy license in those states.

The proposed stipulated penalties for Sunrise Pharmacy, License No. PH03880, are the following: 1) Respondent’s Pharmacy License No. PH03880 has been forfeited because Respondent failed to renew it; 2) Respondent fined $5,000 for the violations; and 3) Respondent assessed $1,000 in attorney’s fees and costs, both to be due and payable on or before February 28, 2026.

The proposed stipulated penalties for Tamara Angeles, Certificate of Registration No.19070, are the following: Respondent’s Certificate of Registration No. 19070 is revoked for a period of one (1) year. The revocation is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; 2) Respondent assessed $1,000 in attorney’s fees and costs; and 3) Respondent shall complete two (2) continuing education hours on duties of a managing pharmacist, in addition to the continuing education hours needed to maintain licensure, and provide certificates of completion to Board staff by July 1, 2026.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Orders for Sunrise Pharmacy and Tamara Angeles as presented by Ms. Tucker.

Second: Krystal Freitas

Action: Passed unanimously.

V. Eric Welling (24-078-CS-S)

Eric Welling was present.

Laura Tucker, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Eric Welling alleging that Respondent Welling failed to disclose on his 2022 controlled substance application renewal that he had been subject to disciplinary action before numerous state boards of medicine.

The proposed stipulated penalties for Eric Welling, Certificate of Registration No. CS33340, are the following: 1) Respondent fined $1,000 for the violation, and 2) Respondent to remain in treatment and counseling as recommended and provide reports to the Board during the duration of his treatment.

Ms. Tucker stated that Respondent Welling has since completed his treatment and counseling and will no longer need to provide PRN-PRN or equivalent evaluations to the Board as part of the stipulation.

Mr. Welling requested the Board that his license be placed in an “inactive” status and that the fine be waived to be paid until he decides whether or not to renew his license.

Todd Weiss, Senior Deputy Attorney General, advised that including such language in the Stipulation and Order is not standard practice.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Eric Welling as presented by Ms. Tucker, with the amendment to paragraph 7, section A to reflect that the fine be due by October 31, 2026, instead of June 3, 2026.

Second: Adam Porath

Action: Passed unanimously.

7. Discussion and possible action on Respondent Gary Royce Wisner, MD's Motion for Reconsideration pursuant to NRS 622A.390(1)(b) in Case No. 22-423-CS-N **(FOR POSSIBLE ACTION)**

Gary Royce Wisner and Jessica R. Gandy (counsel) were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, stated that the Board entered a default order on April 12, 2023, against Respondent Wisner, who was convicted in June 2022 in California on ten (10) felony counts of health care insurance fraud. The Respondent no longer qualifies for a controlled substance registration and his Certificate of Registration No. CS28822 was revoked.

Ms. Gandy stated that Respondent Wisner was unable to attend the initial hearing against his license due to being incarcerated. Respondent Wisner is seeking reconsideration of the revocation order after regaining his license to practice medicine from the Nevada State Board of Medical Examiners.

Mr. Kandt stated his opposition to the motion.

Ms. Gandy stated reasoning why Respondent Wisner was asking for reconsideration and gave background to the Board on how Respondent Wisner is currently serving rural communities.

Todd Weiss, Senior Deputy Attorney General, stated that the Board should first vote on whether or not to open this case up to a hearing before making a final motion.

Ms. Gandy clarified and requested that the Board reconsider the five (5) year period before Dr. Wisner may petition for reinstatement..

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to modify the disciplinary order for Dr. Wisner to state thirty (30) months instead of five (5) years before Dr. Wisner may petition for reinstatement for his controlled substance registration, with the addition that Dr. Wisner does not need to appear before the Board to petition for reinstatement of his registration, provided that his disclosures match his past discipline, and no other concerns are identified by Board staff.

Second: Richard Tomasso

Action: Passed unanimously.

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

W. Cristopher Lipana (23-422-CS-S)

Steven Karen, counsel, was present on behalf of Christopher Lipana.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Cristopher Lipana alleging that Respondent Lipana prescribed dangerous drugs to patients with whom Respondent had not established a bona fide therapeutic relationship, and failed to timely report disciplinary action.

The proposed stipulated penalties for Cristopher Lipana, Certificate of Registration No. CS31815, are the following: Respondent's Certificate of Registration No. CS31815 is suspended for a period of one (1) year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $5,000 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs, both to be due and payable by July 3, 2026; and 3) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Christopher Lipana as presented by Mr. Kandt.

Second: Adam Porath

Action: Passed unanimously.

E. Las Vegas Community Pharmacy (24-133-PH-S)
F. Natalie Nguyen (24-133-RPH-S)
G. Ali Macintosh (24-133-PT-S)

This matter was continued.

I. Darlene Hess (24-460-PTT-S)

This matter was continued.

O. PharMerica (24-370-PH-N)
P. Camilla Kim (24-370-RPH-N)

This matter was continued.

Q. Amy Tseng (24-484-CS-S)

This matter was continued.

W. Michael Stellmacher (24-364-CS-S)

This matter was continued.

X. First Choice Pharmacy (25-110-PH-S)
Y. Nicole Sy (25-110-RPH-A-S)
Z. Kirk Beaulieu (25-110-RPH-B-S)

This matter was continued.

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

A. Prime Plus Lakeview Pharmacy (25-110-V-O)

This matter was continued.

B. Teecee Ann Hailey-Fulfer (25-091-O)

This matter was withdrawn.

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

A. APRX LLC – Las Vegas, NV

Sylvia Durante (Owner) and Paulina Ngo (Managing Pharmacist) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

President Park asked applicants if they would table their application.

This application was tabled.

B. Evergreens Drugs – Henderson, NV

Uttam Beladiya (Manager), Kishan Dholiya (Owner) and Sean Tran (Managing Pharmacist/Current Owner) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the pharmacy license for Evergreens Drugs.

Second: Jade Jacobo

Action: Passed unanimously.

C. Hope Christian Pharmacy – North Las Vegas, NV

Steven Flores (Chief Executive Officer), Nicole Sy (Managing Pharmacist), and Miles Anderson (Chief Operating Officer) were present.

President Park disclosed that she was familiar with Nicole Sy, but she could participate in this matter fairly and without bias.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the pharmacy license for Hope Christian Pharmacy.

Second: Adam Porath

Action: Passed unanimously.

G. M. Rx Pharmacy – Las Vegas, NV

Martha Oppong (Managing Pharmacist and Owner) and Perez Oppong (Owner) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Chanyis Taylor moved to approve the pharmacy license for M. Rx Pharmacy.

Second: Jade Jacobo

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Action: Passed unanimously.

18. Executive Secretary Report

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

17. General Counsel Report

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, and Brett Kandt, General Counsel for the Nevada Board of Pharmacy, presented.

Public comment at January 14, 2026, at 2:16 PM:

There was no public comment.

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

Board Members Present:

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

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Brett Kandt
Laura Tucker	Skylar Young	Todd Weiss	Darlene Nases
Erin Miller	Joe Dodge	Leo Basch	Jessette Phaynarikone
John Castaldo	Darla Zarley	Dena McClish	Ken Scheuber
William Kuykendall	Michael Castaneda	Clayton Bailey	

Call to Order and Roll Call – Establishment of Quorum

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

Public comment at January 15, 2026, at 9:02 AM:

There was no public comment.

◈ WORKSHOP ◈

Thursday, January 15, 2026 – 9:00 am

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

A. Amendment to Chapter 639 of the Nevada Administrative Code. The proposed amendments reduce the minimum age to register to become a pharmaceutical technician in training along with modify certain requirements to become a pharmaceutical technician in training.

David Wuest (Executive Secretary for the Nevada Board of Pharmacy) presented the proposed regulation workshop to the Board.

President Park opened the floor for public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the proposed regulation as presented by Board staff.

Second: Chanyis Taylor

Action: Passed unanimously.

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

A. Proficient Medical, LLC – North Las Vegas, NV

Tafilele P Mauga Jr. (Chief Executive Officer), Thomas Fender III (Chief Operating Officer), Maria “Angie” Mauga (Co-Owner) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada Medical, Devices, Equipment and Gases license for Proficient Medical, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

14. Application for Pharmaceutical Technician Registration (NAC 639.240) – Appearance. (**FOR POSSIBLE ACTION)**

A. Delaney Tabor

Delaney Tabor was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the pharmaceutical technician registration for Delaney Tabor.

Second: Jade Jacobo

Action: Passed unanimously.

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

A. Soren Paape

Soren Paape was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the controlled substance registration for Soren Paape.

Second: Jade Jacobo

Action: Passed unanimously.

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

B. Serendipity Medical Supplies – Las Vegas, NV

Christian Breener was present.

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The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Medical, Devices, Equipment and Gases license for Serendipity Medical Supplies.

Second: Chanyis Taylor

Action: Passed unanimously.

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

C. Golden Health Pharmacy
I. Walgreens Pharmacy #04788 – Carson City, NV
J. Walgreens Pharmacy #09581 – Fallon, NV
K. Walgreens Pharmacy #12488 – Fernley, NV
L. Walgreens Pharmacy #09864 – Gardnerville, NV
M. Walgreens Pharmacy #03871 – Henderson, NV
N. Walgreens Pharmacy #05369 – Henderson, NV
O. Walgreens Pharmacy #05862 – Henderson, NV
P. Walgreens Pharmacy #06424 – Henderson, NV
Q. Walgreens Pharmacy #06545 – Henderson, NV
R. Walgreens Pharmacy #06615 – Henderson, NV
S. Walgreens Pharmacy #07032 – Henderson, NV
T. Walgreens Pharmacy #07164 – Henderson, NV
U. Walgreens Pharmacy #02598 – Las Vegas, NV
V. Walgreens Pharmacy #03841 – Las Vegas, NV
W. Walgreens Pharmacy #03842 – Las Vegas, NV
X. Walgreens Pharmacy #03843 – Las Vegas, NV
Y. Walgreens Pharmacy #03844 – Las Vegas, NV
Z. Walgreens Pharmacy #03872 – Las Vegas, NV
AA. Walgreens Pharmacy #03873 – Las Vegas, NV
BB. Walgreens Pharmacy #03915 – Las Vegas, NV
CC. Walgreens Pharmacy #03922 – Las Vegas, NV
DD. Walgreens Pharmacy #04086 – Las Vegas, NV
EE. Walgreens Pharmacy #04137 – Las Vegas, NV
FF. Walgreens Pharmacy #04197 – Las Vegas, NV

GG. Walgreens Pharmacy #04242 – Las Vegas, NV
HH. Walgreens Pharmacy #04755 – Las Vegas, NV
II. Walgreens Pharmacy #04855 – Las Vegas, NV
JJ. Walgreens Pharmacy #04856 – Las Vegas, NV
KK. Walgreens Pharmacy #05014 – Las Vegas, NV
LL. Walgreens Pharmacy #05015 – Las Vegas, NV
MM. Walgreens Pharmacy #05154 – Las Vegas, NV
NN. Walgreens Pharmacy #05311 – Las Vegas, NV
OO. Walgreens Pharmacy #05570 – Las Vegas, NV
PP. Walgreens Pharmacy #05479 – Las Vegas, NV
QQ. Walgreens Pharmacy #06167 – Las Vegas, NV
RR. Walgreens Pharmacy #06227 – Las Vegas, NV
SS. Walgreens Pharmacy #06310 – Las Vegas, NV
TT. Walgreens Pharmacy #06311 – Las Vegas, NV
UU. Walgreens Pharmacy #06425 – Las Vegas, NV
VV. Walgreens Pharmacy #07450 – Las Vegas, NV
WW. Walgreens Pharmacy #07841 – Las Vegas, NV
XX. Walgreens Pharmacy #07842 – Las Vegas, NV
YY. Walgreens Pharmacy #07864 – Las Vegas, NV
ZZ. Walgreens Pharmacy #10215 – Las Vegas, NV
AAA. Walgreens Pharmacy #10782 – Las Vegas, NV
BBB. Walgreens Pharmacy #10783 – Las Vegas, NV
CCC. Walgreens Pharmacy #10862 – Las Vegas, NV
DDD. Walgreens Pharmacy #11206 – Las Vegas, NV
EEE. Walgreens Pharmacy #11668 – Las Vegas, NV
FFF. Walgreens Pharmacy #11766 – Las Vegas, NV
GGG. Walgreens Pharmacy #11899 – Las Vegas, NV
HHH. Walgreens Pharmacy #12271 – Las Vegas, NV
III. Walgreens Pharmacy #12539 – Las Vegas, NV
JJJ. Walgreens Pharmacy #12641 – Las Vegas, NV
KKK. Walgreens Pharmacy #13900 – Las Vegas, NV
LLL. Walgreens Pharmacy #15035 – Las Vegas, NV
MMM. Walgreens Specialty Pharmacy #15312 – Las Vegas, NV
NNN. Walgreens Pharmacy #21159 – Las Vegas, NV
OOO. Walgreens Pharmacy #12646 – Mesquite, NV
PPP. Walgreens Pharmacy #02590 – North Las Vegas, NV
QQQ. Walgreens Pharmacy #03845 – North Las Vegas, NV
RRR. Walgreens Pharmacy #04854 – North Las Vegas, NV
SSS. Walgreens Pharmacy #05619 – North Las Vegas, NV
TTT. Walgreens Pharmacy #05814 – North Las Vegas, NV

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UUU. Walgreens Pharmacy #10190 – North Las Vegas, NV
VVV. Walgreens Pharmacy #05646 – Pahrump, NV
WWW. Walgreens Pharmacy #02658 – Reno, NV
XXX. Walgreens Pharmacy #02662 – Reno, NV
YYY. Walgreens Pharmacy #04789 – Reno, NV
ZZZ. Walgreens Pharmacy #05295 – Reno, NV
AAAA. Walgreens Pharmacy #11226 – Reno, NV
BBBB. Walgreens Specialty Pharmacy #21237 – Reno, NV
CCCC. Walgreens Pharmacy #02474 – Sparks, NV
DDDD. Walgreens Pharmacy #09902 – Sparks, NV
EEEE. Walgreens Pharmacy #11227 – Sparks, NV
FFFF. Walgreens Pharmacy #12540 – Sparks, NV

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

C. Premise Health Wellness Center – Brentwood, TN
D. Walgreens Pharmacy – Chandler, AZ
E. Walgreens Pharmacy #04580-2 – Miramar, FL
F. Walgreens Pharmacy #02445 – Orlando, FL
G. Walgreens Central Fill #21372 – Tolleson, AZ
H. Walgreens Gene & Cell Services #21574 – Pittsburgh, PA
I. Walgreens Mail Service #03397 – Tempe, AZ
J. Walgreens Specialty Pharmacy #15438 – Canton, MI
K. Walgreens Specialty Pharmacy #15443 – Frisco, TX
L. Walgreens Specialty Pharmacy #16280 – Frisco, TX
M. Walgreens Specialty Pharmacy #21213 – Glendale, AZ
N. Walgreens Specialty Pharmacy #16287 – Pittsburgh, PA
O. Walgreens HUB Solutions #21609 – Pittsburgh, PA

William Stilling (counsel), Michael Simko (counsel), and Rick Gates (Chief Pharmacy Officer for Walgreens) were present.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada pharmacy licenses for Golden Health Pharmacy, Walgreens Pharmacies (76 total), Premise Health Wellness Center, the out-of-state Walgreens Pharmacies (11 total), and Walgreens HUB Solutions.

Second: Adam Porath

Action: Passed unanimously.

Richard Tomasso left the meeting at 10:30 AM.

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

   E. KabaFusion NV – Henderson, NV

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

   A. KabaFusion, LLC – Cerritos, CA
   B. KabaFusion NJ – Edison, NJ

Cory Wages (Director of Operations and Managing Pharmacist), Michael Lee (Associate Vice President for Pharmacy Operations), Smita Njeru (Vice President of Regulatory Compliance), Zahra Alkazaz (Manager of Accreditation Quality), Felicia Vargo-Johnson (Regulatory Compliance Manager), Ellen Paris (Licensing Manager) and Sydney McGuirk (Licensing Specialist) were present.

President Park disclosed that she was familiar with Cory Wages from Roseman University, but that she could participate in this matter fairly and without bias.

The Board heard testimony and asked questions of the applicants.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the out-of-state pharmacy licenses for KabaFusion NV, KabaFusion, LLC, and KabaFusion NJ.

Second: Chanyis Taylor

Action: Passed unanimously.

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

   F. Lovelock Pharmacy – Lovelock, NV

Matthew Christensen, Owner, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Nevada pharmacy license for Lovelock Pharmacy, pending a review of their standard operating procedures by Board staff.

Second: Jade Jacobo

Action: Passed unanimously.

H. Tera Pharmacy – Las Vegas, NV

This matter was tabled.

12. Application for Out-of-State Wholesaler License (NRS 639.233) – Appearance – **(FOR POSSIBLE ACTION)**

A. Stellon Biotech, Inc – Woodcliff Lake, NJ

Sanjeev Krishan, Chief Operating Officer, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the out-of-state wholesaler license for Stellon Biotech, Inc.

Second: Krystal Freitas

Action: Passed unanimously.

13. Application Request for Pharmacist Applicant to Retake the Nevada NAPLEX Exam – Appearance: **(FOR POSSIBLE ACTION)**

A. Ameer Alhaj

Ameer Alhaj was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the request for Ameer Alhaj to retake the Nevada NAPLEX Exam for a seventh time.

Second: Anna Carr

Action: Passed unanimously.

11. Application for Nevada Outsourcing Facility (NRS 639.100) – Appearance (**FOR POSSIBLE ACTION**)

    A. Orion Specialty Labs, LLC – Henderson, NV

This matter was continued.

19. Date and Location of Next Scheduled Board Meeting:

    March 4-5, 2026 – Las Vegas, NV

20. Public Comment

President Park opened the floor for public comment.

There was no public comment.

21. Adjournment

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4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: GastroKlenz, Inc DBA CloudCath

MDEG Physical Address: 665 3rd St. Suite 250

City: San Francisco State: CA Zip: 94107

Mailing Address (if different from physical address): SAME AS PHYSICAL

City: _____ State: _____ Zip: _____

Telephone: 415-484-4896 Website: www.cloudcath.com

Email: accounting@cloudcath.com

Name of MDEG Administrator (NAC 639.694): Eric Yu (Pending)

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

Check the Days the Business will be Opened and provide the Hours of Operation				
☒ Mon: 9am - 5pm PT	☒ Tue: 9am - 5pm PT	☒ Wed: 9am - 5pm PT	☒ Thurs: 9am - 5pm PT	☒ Fri: 9am - 5pm PT
☐ Sat:	☐ Sun:	☐ Holidays:		

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

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

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

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

N/A Exl 11/12/26

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

N/A EM 1/12/2026

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): N/A

Corporation/Organization Name: GastroKlenz, Inc

Mailing Address: 665 3rd St. Suite 250

City: San Francisco State: CA Zip: 94107

Telephone: 415-484-4896 Email: accounting@cloudcath.com

Contact Person Name: Eric Yu

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A EM 1/12/2026

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

N/A EM 1/12/2026

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

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

Eric Yu

Print Name of Authorized Person Submitting Application

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

1/12/2026

Date

Board Use Only	Date Received: 1/20/26	Amount: $500 M038142598342

GASTINC-02 CDRIVER

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 8/20/2025

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

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

PRODUCER
AP Intego Insurance Group, LLC
1601 Trapelo Rd Suite 280
Waltham, MA 02451

CONTACT NAME:
PHONE (A/C, No, Ext):
FAX (A/C, No):
E-MAIL ADDRESS: support@apintego.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Hartford Underwriters Insurance Company	30104
INSURER B : Hartford Fire & Its P&C Affiliates	00914
INSURER C : Continental Casualty Company	20443
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
GastroKlenz, Inc
665 3rd St
Suite 250
San Francisco, CA 94107

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR			76SBUBB5U75	6/1/2025	6/1/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$	
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	Included
	OTHER:							$	
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	
	ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N / A		76WEGAD4MF4	6/1/2025	6/1/2026	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	General Liability -			ADT 8033077358	5/30/2025	5/30/2026	Aggregate		1,000,000

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

CERTIFICATE HOLDER

Proof of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GASTROKLENZ, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF JANUARY, A.D. 2026.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6420548 8300

SR# 20260243386

Authentication: 202890837

Date: 01-22-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment 1

Officers and Directors of GastroKlenz, Inc. DBA CloudCath for Nevada MDEG Application

Officers

- Kelly Constable, Chief Executive Officer
- Eric Yu, Chief Technical Officer
- Don Williamson, Chief Medical Officer
- Mayya Yukilevich, Chief Business Development Officer

Board of Directors:

- Ali Ojjeh
- Aly ElBadry
- Lorenzo Cue
- Amr Salahieh
- Kelly Constable
- Eric Yu
- Jeff Hymes

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

GastroKlenz, Inc.
DBA: CloudCath
665 3rd St Ste 250
San Francisco, CA 94107

LICENSE NUMBER: 111919
EXPIRATION DATE: 7/27/2027

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

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

Outlook

RE: Licensing Requirement Inquiry - December 12, 2025

From FDB MedDevice <FDBMedDevice@cdph.ca.gov>
Date Fri 12/12/2025 11:40 AM
To Channing Jones <cjones@fenwick.com>
Cc Jennifer Yoo <JYoo@fenwick.com>

**** EXTERNAL EMAIL ****
Hello Channing,

Thank you for contacting the California Department of Public Health – Food and Drug Branch about your inquiry. The HMDR license is offered to firms that sell or dispense home medical devices, or DME, to patients via or pursuant a prescription. The license licenses the site where retail sales/distribution activities are performed.

In this scenario, who will be selling the home medical device via prescription to the patients? In other words, who will be charging the patient for their device?

If the manufacturing company in CA is not selling or dispensing the home medical device to patients via or pursuant a prescription, then HMDR licensure would not be required for them.

If the out-of-state 3PL is only shipping or distributing the product and not overseeing the selling or dispensing of the Rx product, then licensure would not be required for the 3PL, either.

If the physician is dispensing the Rx device to the patient and the patient receives the device after it is billed through insurance, for example, no HMDR license is needed, as the physician can dispense the device to the patient directly under the scope of their medical license.

Thank you,
FDB MedDevice

From: Channing Jones <cjones@fenwick.com>
Sent: Friday, December 12, 2025 8:13 AM
To: FDB MedDevice <FDBMedDevice@cdph.ca.gov>
Cc: Jennifer Yoo <JYoo@fenwick.com>
Subject: Licensing Requirement Inquiry - December 12, 2025

You don't often get email from cjones@fenwick.com. Learn why this is important

December 12, 2025

Dear CDPH, Food and Drug Branch,

We are submitting this inquiry on behalf of a company that manufactures a medical device used for at-home peritoneal dialysis to inquire about applicable licensing requirements relating to the shipment of their product directly to patients' homes. The product in question is FDA-cleared and requires a prescription from a physician for a patient to use at-home.

The company is currently licensed in California as a manufacturer of this regulated product and distributes to healthcare providers. Due to issues of scale, the company contracts with a third-party logistics provider (3PL) that is located out of state. The 3PL receives the finished products from the California-based manufacturing facility and subsequently fulfills and ships any orders to recipient providers located in California.

The company, through the services of its contracted 3PL, is now hoping to deliver the devices directly to patients for at-home use, pursuant to a physician's prescription.

Under these circumstances, would the company be required to obtain a "Home Medical Device Retailer License" even if the company is not selling directly to patients (just delivering directly to patients)? If so, would it be sufficient for the license to be connected to the CA manufacturing location or does the out of state 3PL location need the HMDR out of state license?

Additionally, based on prior informal guidance from the CA Board of Pharmacy, our understanding is that the California Business and Professions Code §4054 provides an exemption to the wholesaler license requirement for at-home dialysis drugs and devices. However, we would appreciate written confirmation from CDPH, or other direction to the appropriate licensing authority, to ensure the company is in compliance with California regulations.

The company understands the importance of proper licensing oversight and aims to fully comply with any applicable statutes and regulations. Your guidance on whether the HMDR license is required, §4054 exemption applies in this context, and whether any further licensing is required, would be greatly appreciated.

Thank you for your time and consideration.

Very respectfully,
Channing Jones

Channing Jones
Fenwick | Law Clerk, Not yet admitted to the practice of law. | +1 202-970-3049 | CJones@fenwick.com

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NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: GastroKlenz, Inc DBA CloudCath

Pharmacy/MDEG/Wholesaler License # (if applicable): TBD

Physical Address: 665 3rd St. Suite 250

City: San Francisco State: CA Zip: 94107

Mailing Address (if different from physical address): SAME AS PHYSICAL

City: State: Zip:

Telephone: 415-484-4896 Website: cloudcath.com

Licensing Company Email: accounting@cloudcath.com

Section 2: Personal Information

First: Eric Middle: H Last: Yu

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

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

Mailing Address: [redacted]

City: [redacted] State: CA Zip: [redacted]

Telephone: [redacted] Email: eric@cloudcath.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Stanford University		03/04-03/06	
Address	**City**	**State**	**Zip**
450 Jane Stanford Way	Stanford	CA	94305
Diploma/Degree obtained, if any			
M.S. in Mechanical Engineering - focus on Design Methodology and Biodesign			

School Name		From - To (MM/YY – MM/YY)	
University of California, Berkeley		05/00 - 05/04	
Address	**City**	**State**	**Zip**
110 Sproul Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
B.S in Mechanical Engineering, Minor in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Campolindo High School		08/96 - 06/00	
Address	**City**	**State**	**Zip**
300 Moraga Rd	Moraga	CA	94556
Diploma/Degree obtained, if any			
High School Diploma			

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

N/A EY 1/12/2026

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23 - CURRENT	[redacted]	[redacted]	CA	[redacted]
05/12 - 11/23	[redacted]	[redacted]	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A EY 1/12/2026

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

Business Name			From - To (MM/YY – MM/YY)	
GastroKlenz, Inc DBA CloudCath`			01/17 - Present	
Business Address		**City**	**State**	**Zip**
665 3rd St. Suite 250		San Francisco	CA	94107
Phone	**Title**			
415-484-4896	Chief Technical Officer			

Description of Duties
Managed clinical study design and execution to collect and measure effluent samples to develop the system measurement algorithms for infection detection. Developed protocol, measurement procedures; analyzed data; lead data science team in feature engineering process and correlation analysis.
• Lead design of electro-mechanical sensing system for monitoring infections in peritoneal dialysis patients, firmware development IoT device with on-board cellular modem communicating with AWS serverless backend. Lead design of sterile daily use disposable fluid conduit and measurement window.

Business Name			From - To (MM/YY – MM/YY)	
Eric Yu, Independent Engineering Consulting			07/15-01/17	
Business Address		**City**	**State**	**Zip**
[redacted]		[redacted]	CA	[redacted]
Phone	**Title**			
415-902-6499	Principal Engineer			

Description of Duties

Engineering design services for medical device development, servicing clients including Medtronic Neurovascular, Forsight Vision 5, Medina Medical

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

Description of Duties

N/A EY 1/12/26

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

EY 1/12/22

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

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

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

Provide explanation below:

N/A

EY 1/12/2026

_____ _____

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

EY 1/12/26

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

Eric Yu
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/12/2026
Date

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

State of California, ss. County of San Francisco

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

Original Signature

1/12/2026
Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

Notary Certificate Attached / Affixed Pursuant
☐ CA Ack Code - Gov § 1189
☒ CA Jurat Code - Gov § 8202

(Seal)

EY 1/12/26

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of San Francisco

Subscribed and sworn to (or affirmed) before me on this 12th (Date) day of January (Month), 2026 (Year), by

(1) Eric Hsiang Yu

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.



Signature _____
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Personal History Application

Document Date: January 12th 2026 Number of Pages: 7

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site GastroKlenz, Inc DBA CloudCath

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) TBD

Physical Address 665 3rd St. Suite 250

City San Francisco State CA Zip 94107

Mailing Address (if different from physical address) SAME AS PHYSICAL

City _____ State _____ Zip _____

Telephone 415-484-4896 Website CLOUDCATH.COM

Licensing Company Email accounting@cloudcath.com

Section 2: Personal Information

First Ali Middle _____ Last Albadri

Alias(es, nicknames, name changes, etc.) Aly ElBadry

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

Mailing Address [redacted]

City [redacted] State CA Zip [redacted]

Telephone [redacted] Email aly@cloudcath.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Stanford University		09/15-06/17	
Address	**City**	**State**	**Zip**
450 Jane Stanford Way	Stanford	CA	94305
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Aston University		08/08 - 06/12	
Address	**City**	**State**	**Zip**
Aston St	Birmingham	England	B4 7ET
Diploma/Degree obtained, if any			
Bachelors in Eng, Electrical and Electronic Engineering (1st Class Honors Degree)			

School Name		From - To (MM/YY – MM/YY)	
Cairo American College		08/05-06/07	
Address	**City**	**State**	**Zip**
Midan Digla Maadi 1 Street 253	Maadi	Cairo	11431
Diploma/Degree obtained, if any			
International Baccaleaureate Full Bilingual Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/25-Present	[redacted]	[redacted]	FL	[redacted]
08/24 - 08/25			FL	
08/17 - 08/24			CA	
08/15 - 08/17			CA	

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

Business Name			From - To (MM/YY – MM/YY)	
GastroKlenz, Inc DBA CloudCath			09/16 - 06/25	
Business Address		**City**	**State**	**Zip**
665 3rd St. Suite 250		San Francisco	CA	94107
Phone	**Title**			
415-484-4896	Chief Executive Officer			
Description of Duties				
Reporting to the Board of Directors, the CEO oversees aspects of the organization including finances, business development, and plan and policy management.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

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

Ali Albadri

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/12/2026

Date

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

State of Florida, ss. County of Miami-Dade

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

Original Signature

Date

Subscribed and Sworn to before me this 12 day of January 2026

Notary Public Signature

RAMON VARGAS
Notary Public
State of Florida
Comm# HH647272
Expires 3/11/2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG GastroKlenz, Inc DBA CloudCath MDEG License # (if applicable) _____

Physical Address 665 3rd St. Suite 250

City San Francisco State CA Zip 94106

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 415-484-4896 Website www.cloudcath.com

Licensing Company Email accounting@cloudcath.com

Section 2: Personal Information

First Eric Middle H Last Yu

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

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

Mailing Address [redacted]

City [redacted] State CA Zip [redacted]

Telephone [redacted] Email eric@cloudcath.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Stanford University		03/04 - 03/06	
Address	**City**	**State**	**Zip**
450 Jane Stanford Way	Stanford	CA	94305
Diploma/Degree obtained, if any			
M.S. in Mechanical Engineering - focus on Design Methodology and Biodesign			

School Name		From - To (MM/YY – MM/YY)	
University of California, Berkeley		05/00 - 05/04	
Address	**City**	**State**	**Zip**
110 Sproul Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
B.S in Mechanical Engineering, Minor in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Campolindo High School		08/96 - 06/00	
Address	**City**	**State**	**Zip**
300 Moraga Rd	Moraga	California	94556
Diploma/Degree obtained, if any			
High School Diploma			

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

EM 1/12/2024

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23-CURRENT	[redacted]	[redacted]	CA	[redacted]
From - To (MM/YY – MM/YY)			State	
05/12-11/23			CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

EM 1/12/2024

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

Business Name			From - To (MM/YY – MM/YY)
GastroKlenz, Inc DBA CloudCath			01/17- Present
Business Address	**City**	**State**	**Zip**
665 3rd St. Suite 250	San Francisco	CA	94107
Phone	**Title**		**Number of Employed Hours**
415-484-4896	Chief Technical Officer, Co-Founder		16492 total

Description of Duties
• Managed clinical study design and execution to collect and measure effluent samples to develop the system measurement algorithms for infection detection. Developed protocol, measurement procedures; analyzed data; lead data science team in feature engineering process and correlation analysis.
• Lead design of electro-mechanical sensing system for monitoring infections in peritoneal dialysis patients, firmware development IoT device with on-board cellular modem communicating with AWS serverless backend. Lead design of sterile daily use disposable fluid conduit and measurement window.

Business Name			From - To (MM/YY – MM/YY)
Eric Yu, Independent Engineering Consulting			07/15- 01/17
Business Address	**City**	**State**	**Zip**
[redacted]	[redacted]	CA	[redacted]
Phone	**Title**		**Number of Employed Hours**
415-902-6499	Principal Engineer		3100 total

Description of Duties
Engineering design services for medical devices, servicing clients including Medtronic Neurovascular, Forsight Vision 5, Medina Medical

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

Description of Duties

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

Description of Duties

EM 11/12/2024

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

N/A CM 1/12/2026

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

I, Eric Yu **, certify that as the MDEG Administrator for**

GastroKlenz, Inc DBA CloudCath ,

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

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

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

Eric Yu
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/12/2026
Date

Board Use Only	Date Received: 1/20/26

4B

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Geodis Logistics LLC

MDEG Physical Address: 1101 Whitaker Rd

City: Plainfield State: IN Zip: 46168

Mailing Address (if different from physical address): 7101 Executive Center Dr

City: Brentwood State: TN Zip: 37027

Telephone: 317-779-4145 Website: www.geodis.com

Email: licensing.cl.us@geodis.com

Name of MDEG Administrator (NAC 639.694): Stephen Harder

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions	☐ Medical Gases**
■ Pharmacies[a]	☐ Respiratory Equipment**
■ Practitioners[a]	☐ Life-sustaining equipment**
■ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: orthopedic equipment
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Stephen Harder
	Telephone: 317-779-4145

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 7am - 5pm	■ Tue: 7am - 5pm	■ Wed: 7am - 5pm	■ Thurs: 7am - 5pm	■ Fri: 7am - 5pm
☐ Sat:	☐ Sun:	☐ Holidays:		

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

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

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

Name: n/a Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee

Parent Company (if any): Ozburn-Hessey Holding Company, LLC

Corporation/Organization Name: Geodis Logistics LLC

Mailing Address: 7101 Executive Center Dr

City: Brentwood State: TN Zip: 37207

Telephone: 615-401-6400 Email: licensing.cl.us@geodis.com

Contact Person Name: Mark Vane

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Stephen Harder

Print Name of Authorized Person Submitting Application

S. Harder

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

11-25-2025

Date

Board Use Only	Date Received: 12/8/25	Amount: $500-cc

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/2/2026

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

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

PRODUCER
Arthur J. Gallagher Risk Management Services, LLC
12444 Powerscourt Dr Ste 500
St. Louis MO 63131

CONTACT NAME: Sandy Gross
PHONE (A/C, No, Ext): 314-800-2269 **FAX (A/C, No):**
E-MAIL ADDRESS: sandy_gross@ajg.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : XL Insurance America, Inc.	24554
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED GEODLOG-01
GEODIS LOGISTICS LLC
7101 Executive Center Drive, Suite 333
Brentwood, TN 37027

COVERAGES **CERTIFICATE NUMBER:** 747714848 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY	Y	Y	US00108264LI26A	1/1/2026	1/1/2027	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR	Y	Y	US00108265LI26A	1/1/2026	1/1/2027	EACH OCCURRENCE	$ 1,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 1,000,000
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N/A						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Limit is at least the limit shown on the policy
Locations: 1100 Whitaker Road, Plainfield, IN; 1101 Whitaker Road, Plainfield, IN; 1250 S. Perry Road, Plainfield, IN; 2450 Stanley Road, Plainfield, IN
OVB Indianapolis Industrial, LLC, BOP Management, LLC and is related interests and Colliers International Indiana, LLC are included as Additional Insureds as respects General Liability and Umbrella Liability policies, pursuant to and subject to the policy's terms, definitions, conditions and exclusions. Waiver of Subrogation is granted in favor of Certificate Holder in accordance with the policy provisions of the General Liability and Umbrella Liability policies.

CERTIFICATE HOLDER

OVB Indianapolis Industrial, LLC
c/o BIP Management, LLC
222 South 9th Street, Suite 2870
Minneapolis MN 55402

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
Craig R Parris

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CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 11/14/2025

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Services South, Inc. Franklin TN Office 501 Corporate Centre Drive Suite 300 Franklin TN 37067 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Liberty Mutual Fire Ins Co	23035
INSURER B:	LM Insurance Corporation	33600
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Geodis Logistics LLC
7101 Executive Center Dr
Suite 333
Brentwood TN 37027 USA

COVERAGES **CERTIFICATE NUMBER:** 570116666299 **REVISION NUMBER:**

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

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY CLAIMS-MADE / OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY / PRO-JECT / LOC OTHER:						EACH OCCURRENCE	
							DAMAGE TO RENTED PREMISES (Ea occurrence)	
							MED EXP (Any one person)	
							PERSONAL & ADV INJURY	
							GENERAL AGGREGATE	
							PRODUCTS - COMP/OP AGG	
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY			AS2-651-291883-015	11/01/2025	11/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$2,000,000
							BODILY INJURY (Per person)	
							BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB / OCCUR EXCESS LIAB / CLAIMS-MADE DED / RETENTION						EACH OCCURRENCE	
							AGGREGATE	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WA565D291883035 AOS	11/01/2025	11/01/2026	X PER STATUTE / OTH-ER	
B				WC5651291883025 WI & MN	11/01/2025	11/01/2026	E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

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

RE: Location: 1101 Whitaker Road, Plainfield, IN, 1251 S. Perry Road, Plainfield, IN 2450 Stanley Road, Plainfield, IN.

CERTIFICATE HOLDER

OVB Indianapolis Industrial, LLC
c/o BIP Management, LLC
222 South 9th Street, Suite 2870
Minneapolis MN 55402 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Services South Inc.

Holder Identifier :

Certificate No : 570116666299

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Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
sos.tn.gov/

Tre Hargett
Secretary of State

ERICA TARRANT-WILSON
[redacted]
WILMINGTON, DE 19808, USA

12/12/2025

Request Type: Certificate of Existence/Authorization
Issuance Date: 12/12/2025

Request #: C2025110176

Document Receipt

Order Number: C2025110176
Verification #: E700B496
Receipt #: 2025-815494
Filing Fee: $20.00
Payment: Credit Card - [redacted] $20.00

Entity Name:	GEODIS LOGISTICS LLC		
SOS Control #:	000307202	Initial Filing Date:	02/08/1996
Entity Type:	Limited Liability Company (LLC)	Formation Locale:	TENNESSEE
Status:	Active	Duration Term:	Perpetual
Fiscal Year Close:	December	Annual Report Due:	04/01/2026
Business County:	WILLIAMSON		
Managed By:	Board Managed		
Obligated Member Entity:	No		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

GEODIS LOGISTICS LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;
* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
* has filed the most recent annual report required with this office;
* has appointed a registered agent and registered office in this State;
* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Verification #: E700B496

GEODIS
We logistic your growth

GEODIS LOGISTICS LLC
7101 Executive Center Drive
Brentwood, TN 37027
(615)401-6400
Organized in Tennessee on 02/08/1996

Sole Member, Parent Company, and 100% Owner is Ozburn-Hessey Holding Company, LLC

Officers:

Laura Ritchey - President and CEO
laura.ritchey@geodis.com
7101 Executive Center Drive, Brentwood, TN 37027

Jeremy Wright - EVP & Chief Financial Officer
jeremy.wright@geodis.com
7101 Executive Center Drive, Brentwood, TN 37027

Mark Vane - Chief Legal Officer and Secretary
mark.vane@geodis.com
7101 Executive Center Drive, Brentwood, TN 37027

Details

GEODIS LOGISTICS LLC

Entity Type: Limited Liability Company (LLC)
Formed in: TENNESSEE
Term of Duration: Perpetual
Managed By: Board Managed
Series LLC: No
Number of Members: 6 or less
Status: Active
Control Number: 000307202
Initial Filing Date: 2/8/1996 3:48:00 PM
Fiscal Ending Month: December
AR Due Date: 04/01/2026
Obligated Member Entity: No

Registered Agent
CORPORATION SERVICE COMPANY
2908 POSTON AVE
NASHVILLE, TN 37203-1312
Principal Office Address
7101 EXECUTIVE CENTER DR SUITE 333
BRENTWOOD, TN 37027-3283
Mailing Address
7101 EXECUTIVE CENTER DR SUITE 333
BRENTWOOD, TN 37027-3283

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000073A	09/30/2026

Geodis Logistics LLC
1101 Whitaker Road
Plainfield IN 46168

Eric J. Holcomb
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000073A	09/30/2026

Geodis Logistics LLC

Signature

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Geodis Logistics LLC — MDEG License # (if applicable): _____

Physical Address: 1101 Whitaker Rd

City: Plainfield — State: IN — Zip: 46168

Mailing Address (if different from physical address): 7101 Executive Center Dr

City: Brentwood — State: TN — Zip: 37027

Telephone: 317-779-4145 — Website: www.geodis.com

Licensing Company Email: licensing.cl.us@geodis.com

Section 2: Personal Information

First: Stephen — Middle: Henry — Last: Harder

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

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

Mailing Address: [redacted]

City: [redacted] — State: _____ — Zip: [redacted]

Telephone: 317-779-4145 — Email: licensing.cl.us@geodis.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas at Little Rock		08/93 - 08/94	
Address	**City**	**State**	**Zip**
2801 S University Ave	Brentwood	TN	37207
Diploma/Degree obtained, if any			
BA of Arts			

School Name		From - To (MM/YY – MM/YY)	
Memorial High School		08/80 - 05/84	
Address	**City**	**State**	**Zip**
2104 S Indiana Ave	Joplin	MO	64804
Diploma/Degree obtained, if any			
HS Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - Present	[redacted]	[redacted]	IN	[redacted]
05/16 - 12/18			IN	

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

Business Name			From - To (MM/YY – MM/YY)	
Geodis Logistics LLC			04/11 - Present	
Business Address		**City**	**State**	**Zip**
1101 Whitaker Rd		Plainfield	IN	46168
Phone	**Title**		**Number of Employed Hours**	
214-779-4145	Director of Operations		29,120	
Description of Duties				
Manage healthcare related distribution facility containing multiple medical device, pharmaceutical, OTC and food accounts; oversee financial performance and operational compliance/processes.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

S. Hardin

Original Signature (electronic, copies or stamps not accepted)

11-25-2025

Date

I, Stephen Harder, **certify that as the MDEG Administrator for**

_____,

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

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

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

Stephen Harder
Print Name (First, Last)

S. Harder
Original Signature (electronic, copies or stamps not accepted)

11-25-2025
Date

Board Use Only	Date Received: 12/8/25

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Geodis Logistics LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH01627

Physical Address: 1101 Whitaker Rd

City: Plainfield State: IN Zip: 46168

Mailing Address (if different from physical address): 7101 Executive Center Dr

City: Brentwood State: TN Zip: 37027

Telephone: 317-779-4145 Website: www.geodis.com

Licensing Company Email: licensing.cl.us@geodis.com

Section 2: Personal Information

First: Stephen Middle: Henry Last: Harder

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

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

Mailing Address: [redacted]

City: [redacted] State: IN Zip: [redacted]

Telephone: 317-779-4145 Email: stephen.harder@geodis.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas at Little Rock		08/93 - 08/94	
Address	**City**	**State**	**Zip**
2801 S University Ave	Little Rock	AR	72204
Diploma/Degree obtained, if any			
BA of Arts			

School Name		From - To (MM/YY – MM/YY)	
Memorial High School		08/80 - 05/84	
Address	**City**	**State**	**Zip**
2104 S Indiana Ave	Joplin	MO	64804
Diploma/Degree obtained, if any			
HS Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - Present	[redacted]	[redacted]	IN	[redacted]
05/16 - 12/18	[redacted]	[redacted]	IN	[redacted]

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

Business Name			From - To (MM/YY – MM/YY)
Geodis Logistics LLC			04/11 - Present
Business Address	**City**	**State**	**Zip**
1101 Whitaker Rd	Plainfield	IN	46168
Phone	**Title**		
214-779-4145	Director of Operations		

Description of Duties

Manage healthcare related distribution facility containing multiple medical device, pharmaceutical, OTC and food accounts; oversee financial performance and operational compliance/processes.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

S. Hardin

Original Signature (electronic, copies or stamps not accepted)

11-25-2025

Date

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

Stephen Harder

Print Name (First, Last)

S. Harder

Original Signature (electronic, copies or stamps not accepted)

11-25-2025

Date

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

State of _____, ss. County of _____

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

S. Harder

Original Signature

11-25-2025

Date

Subscribed and Sworn to before me this 25 day of November, 2025

Darlene S. Rose

Notary Public Signature

NOTARY PUBLIC - STATE OF INDIANA
SEAL
DARLENE S ROSE
COMMISSION NUMBER NP0681598
MY COMMISSION EXPIRES MARCH 10, 2032

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Geodis Logistics LLC

Pharmacy/Wholesaler License # (if applicable): WHO1627

Physical Address: 1101 Whitaker Rd

City: Plainfield State: IN Zip: 46168

Mailing Address (if different from physical address): 7101 Executive Center Dr

City: Brentwood State: TN Zip: 37027

Telephone: 317-779-4145 Website: www.geodis.com

Licensing Company Email: licensing.cl.us@geodis.com

Section 2: Personal Information

First: Stephen Middle: Henry Last: Harder

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

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

Mailing Address: [redacted]

City: [redacted] State: Indiana Zip: [redacted]

Telephone: 317-779-4145 Email: stephen.harder@geodis.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Arkansas at Little Rock		08/93 - 08/94	
Address	**City**	**State**	**Zip**
2801 S University Ave	Little Rock	AR	72204
Diploma/Degree obtained, if any			
BA of Arts			

School Name		From - To (MM/YY – MM/YY)	
Memorial High School		08/80 - 05/84	
Address	**City**	**State**	**Zip**
2104 S Indiana Ave	Joplin	MO	64804
Diploma/Degree obtained, if any			
HS Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - Present	[redacted]	[redacted]	IN	[redacted]
05/16 - 12/18	[redacted]	[redacted]	IN	[redacted]

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Geodis Logistics LLC			04/11 - Present	
Business Address		**City**	**State**	**Zip**
1101 Whitaker Rd		Plainfield	IN	46168
Phone	**Title**		**Number of Employed Hours**	
317-779-4145	Director of Operations		29,120	
Description of Duties				
Manage healthcare related distribution facility containing multiple medical device, pharmaceutical, OTC and food accounts; oversee financial performance and operational compliance/processes.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

S. Hamdi

Original Signature (electronic, copies or stamps not accepted)

11-25-2025

Date

I, Stephen Harder, **certify that as the designated representative for**

Geodis Logistics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Stephen Harder

Print Name (First, Last)

S Harder

Original Signature (electronic, copies or stamps not accepted)

11-25-2025

Date

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

Stephen Harder

Print Name (First, Last)

S. Harder

Original Signature (electronic, copies or stamps not accepted)

11-25-25

Date

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

State of Indiana, ss. County of Hendricks

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

S. Harder

Original Signature

11-25-2025

Date

Subscribed and Sworn to before me this 25 day of November, 2025

Darlene S. Rose

Notary Public Signature

NOTARY PUBLIC - STATE OF INDIANA
SEAL
DARLENE S ROSE
COMMISSION NUMBER NP0681598
MY COMMISSION EXPIRES MARCH 10, 2032

(Seal)

4C

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: INTOUCH MED SUPPLY LLC

MDEG Physical Address: 215 WEST CHURCH ROAD, SUITE 102

City: KING OF PRUSSIA State: PA Zip: 19406

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-412-0370 Website: WWW.INTOUCHMEDSUPPLY.COM

Email: SUPPORT@INTOUCHMED SUPPLY.COM

Name of MDEG Administrator (NAC 639.694): _____

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9AM - 5PM	■ Tue: 9AM - 5PM	■ Wed: 9AM - 5PM	■ Thurs: 9AM - 5PM	☐ Fri: 9AM - 5PM
☐ Sat: APPT ONLY	☐ Sun:	■ Holidays: PHONE		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
7697320001 - MEDICARE

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

Name: NA _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: LANCE MARQUARDT, CEO

Business Name: INTOUCH MED SUPPLY LLC

Business Address: 215 WEST CHURCH ROAD, SUITE 102

City: KING OF PRUSSIA State: PA Zip: 19406

Telephone: 888-412-0370 Email: SUPPORT@INTOUCHMEDSUPPLY.COM

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

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

LANCE MARQUARDT

Print Name of Authorized Person Submitting Application

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

DEC 16, 2025

Date

Board Use Only	Date Received: 12/17/25	Amount: $500.00

INTOMED-01 ESMITH1

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/21/2025

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

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

PRODUCER License # BR-767175
Hub International Northeast Limited
1805 Loucks Road, Suite 100
York, PA 17408

CONTACT NAME: Emily Smith
PHONE (A/C, No, Ext): (717) 767-7859 FAX (A/C, No):
E-MAIL ADDRESS: emily.smith@hubinternational.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Arch Insurance Company	11150
INSURER B : Hartford Insurance Group	914
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Intouch Med Supply LLC
215 W Church Road
Suite 102
King Of Prussia, PA 19406

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY							
	CLAIMS-MADE X OCCUR			MHPK09404907	5/22/2025	5/22/2026	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY							
	ANY AUTO						COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	OWNED AUTOS ONLY X SCHEDULED AUTOS			MHPK09404907	5/22/2025	5/22/2026	BODILY INJURY (Per person)	$
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$ 1,000,000
	EXCESS LIAB CLAIMS-MADE			MHUM07271303	5/22/2025	5/22/2026	AGGREGATE	$ 1,000,000
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A		13WECAC5HJ9	12/17/2024	12/17/2025	E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	Professional Liabili			MHPK09404907	5/22/2025	5/22/2026	per occurence	1,000,000
A	Professional Liabili			MHPK09404907	5/22/2025	5/22/2026	Aggregate	3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Certificate is evidence of insurance for the named insured, subject to terms, conditions and exclusions.

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
Emily C Smith

ACORD 25 (2016/03)

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Pennsylvania Department of State

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

Regarding:	INTOUCH MED SUPPLY LLC
Request Type:	Subsistence Certificate
Request No.:	068811829
Receipt No.:	002317694
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	April 12, 2018
Status:	Active

Issuance Date: December 01, 2025
File No.: 0006698358

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

INTOUCH MED SUPPLY LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

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

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

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

Albert Schmidt
Secretary of the Commonwealth

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

Certificate of Registration

Certificate No. 6000009358
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Devices

Drug & Device Registration
2525 N. 7th Street
Suite 210D
HARRISBURG, PA 17110
(717) 787-4779

INTOUCH MED SUPPLY
215 WEST CHURCH RD
SUITE 102
KING OF PRUSSIA, PA 19406

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: May 17, 2018
Expiration Date: The Last Day of June, 2026

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site INTOUCH MED SUPPLY LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 215 WEST CHURCH ROAD, SUITE 102

City KING OF PRUSSIA State PA Zip 19406

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-412-0370 Website WWW.INTOUCHMEDSUPPLY.COM

Licensing Company Email SUPPORT@INTOUCHMEDSUPPLY.COM

Section 2: Personal Information

First LANCE Middle S Last MARQUARDT

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

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

Mailing Address [redacted]

City [redacted] State PA Zip [redacted]

Telephone [redacted] Email SUPPORT@INTOUCHMEDSUPPLY.COM

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
PENNSYLVANIA STATE UNIVERSITY		08/01/97 -- 05/01/22	
Address	**City**	**State**	**Zip**
201 OLD MAIN	UNIVERSITY PARK	PA	18602
Diploma/Degree obtained, if any			
BUSINESS MANAGEMENT			

School Name		From - To (MM/YY – MM/YY)	
BISHOP O'REILLY		08/01/93 -- 06/01/97	
Address	**City**	**State**	**Zip**
316 N MAPLE AVENUE	KINGSTON	PA	18704
Diploma/Degree obtained, if any			
HIGH SCHOOL			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/22 – 12/25 CUR	[redacted]	[redacted]	PA	[redacted]
04/18 – 08/22			PA	
11/15 – 04/18			PA	

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

Business Name			From - To (MM/YY – MM/YY)
INTOUCH MED SUPPLY LLC			04/18 -- 12/25 CURRE
Business Address	**City**	**State**	**Zip**
215 WEST CHURCH ROAD, SUITE 102	KING OF PRUSSIA	PA	19406
Phone	**Title**		
888-412-0370	FOUNDER & CEO		

Description of Duties

Administration of daily activities related to fulfillment, compliance, finance, patient care & accreditation since inception.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

/NA

_____ Dec 16, 2025

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

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

LANCE MARQUARDT

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Dec 16, 2025

Date

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

State of Pennsylvania, ss. County of Montgomery

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

Original Signature

Dec 16, 2025

Date

Subscribed and Sworn to before me this 16th day of December.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
TERRANCE BRUNSON - Notary Public
Montgomery County
My Commission Expires March 12, 2029
Commission Number 1457333

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG INTOUCH MED SUPPLY LLC MDEG License # (if applicable) _____

Physical Address 215 WEST CHURCH ROAD, SUITE 102

City KING OF PRUSSIA State PA Zip 19406

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email SUPPORT@INTOUCHMEDSUPPLY.COM

Section 2: Personal Information

First LANCE Middle S Last MARQUARDT

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

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

Mailing Address [redacted]

City [redacted] State PA Zip [redacted]

Telephone [redacted] Email LANCEM@INTOUCHMEDSUPPLY.COM

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
PENNSYLVANIA STATE UNIVERSITY		08/01/97 -- 05/01/22	
Address	**City**	**State**	**Zip**
201 OLD MAIN	UNIVERSITY PARK	PA	18602
Diploma/Degree obtained, if any			
BUSINESS MANAGEMENT			

School Name		From - To (MM/YY – MM/YY)	
BISHOP O'REILLY		08/01/93 -- 06/01/97	
Address	**City**	**State**	**Zip**
316 N MAPLE AVENUE	KINGSTON	PA	18704
Diploma/Degree obtained, if any			
HIGH SCHOOL			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/22 -- 12/25 CUR	[redacted]	[redacted]	PA	[redacted]
04/18 -- 08/22			PA	
11/15 -- 04/18			PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
INTOUCH MED SUPPLY LLC			04/18 -- 12/25 CURRE
Business Address	**City**	**State**	**Zip**
215 WEST CHURCH ROAD, SUITE 102	KING OF PRUSSIA	PA	19406
Phone	**Title**		**Number of Employed Hours**
888-412-0370			26,250 HRS
Description of Duties			
Administration of daily activities related to fulfillment, compliance, finance, patient care & accreditation since inception.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Dec 16, 2025
Date

I, LANCE MARQUARDT, **certify that as the MDEG Administrator for**

INTOUCH MED SUPPLY, LLC,

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

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

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

LANCE MARQUARDT

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Dec 16, 2025

Date

Board Use Only	Date Received: 12/17/25

4D

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Medline Industries, LP

MDEG Physical Address: 239 Belvidere Road

City: Perryville State: MD Zip: 21903

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

City: Northfield State: IL Zip: 60093

Telephone: 410-642-2020 Website: https://www.medline.com/

Email: ralicensing@medline.com

Name of MDEG Administrator (NAC 639.694): Mark Rizzo

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

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

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

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
See Attachment 2

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Medline Industries, LP

Mailing Address: Three Lakes Drive #3D

City: Northfield State: IL Zip: 60093

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

Contact Person Name: Kiara Rosado

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** Attachment 3	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).** Attachment 3			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.** Attachment 4	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).** Attachment 5	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00). Attachment 6	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/ N/A No individual owners, refer to Attachment 3		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/ Attachment 7	✓	✓	✓	✓

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

Lara N. Simmons, Chief Quality Officer

Print Name of Authorized Person Submitting Application

Lara N Simmons

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

12/02/2025

Date

Board Use Only	Date Received: 12/15/25	Amount: $500.00

Attachment 1

Medline Industries, LP- Discipline *Confidential*

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

Attachment 1 (cont.)

Medline Industries, LP- Discipline *Confidential*

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

Attachment 1 (cont.)

Medline Industries, LP- Discipline *Confidential*

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

Attachment 2

Medicare Enrollments (1)

Provider Name	Enrollment State	Enrollment Status	Provider ID
Medline Industries, LP	IL	Active	0428930001

Medicaid Enrollments (1)

Provider Name	Enrollment State	Enrollment Status	Provider ID
Medline Industries, LP	FL	Active	119444000

Attachment 6

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/16/2025

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

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

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

CN101705524-Stnd-GAWUP-25-26 USA

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

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

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Safety National Casualty Corporation	15105
INSURER B : Endurance Assurance Corporation	11551
INSURER C : See Acord 101 for Carrier Participation	
INSURER D :	
INSURER E :	
INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-008956355-44 **REVISION NUMBER:** 80

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL 4065036	07/01/2025	07/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 2,000,000 10,000 2,000,000 4,000,000 SEE BELOW
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA 6675933	07/01/2025	07/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	2,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 10,000			ELD10004065212	07/01/2025	07/01/2026	EACH OCCURRENCE AGGREGATE	$ $	10,000,000 10,000,000
A A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N: Y If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		LDS 4065032 (AOS) PS 4065034 (WI)	07/01/2025 07/01/2025	07/01/2026 07/01/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00613-25	07/01/2025	07/01/2026	Limit		2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569.
SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.
Evidence of Insurance.

CERTIFICATE HOLDER

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

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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Attachment 6 (cont.)

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

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

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Products/Completed Operations Liability Carrier Participation:
57.86% of the layer is insured by Lloyds of London
17.14% of the layer is insured by AXA XL UK Ltd. (A+)
25% of the layer is insured by Harleysville Insurance Company of NY (A)

LOCATION ADDRESS CITY STATE ZIP CODE
B01 1 Medline Pl. Mundelein Illinois 60060
B04 1160 S Northpoint Blvd S . Waukegan Illinois 60085
B04 1710 S Lakeside Dr. Waukegan Illinois 60085
B04 1170 S Northpoint Blvd S. Waukegan Illinois 60085
B06 1 Medline Dr. Wilmer Texas 75172
B11 21111 E 36th Dr. Aurora Colorado 80011
B18 1062 Fasken Blvd. Laredo Texas 78045
B22 9670 NW 112 Ave. Medley Florida 33178
B24 8001 SW 47th St. Oklahoma City Oklahoma 73179
B25 1401 N Universal Ave. Kansas City Missouri 64120
B27 92 SE 223rd Ave. Gresham Oregon 97030
B28 735 County Rd 4 E. Prattville Alabama 36067
B29 13115 Brockton Lane N. Rogers Minnesota 55374
B30 1900 Meadowville Technology Parkway. Chester Virginia 23836
B31 500 Sharkey Dr. Maumelle Arkansas 72113
B34 9051 King St. Anchorage Alaska 99518
B36 1989 Transit Way. Brockport New York 14420
B44 2325 W Louise Ave. Manteca California 95337
B45 1119 W Middlesex Ave Bldg 4. Port Reading New Jersey 07064
B48 36445 Van Born Road, Suite 200 Romulus Michigan 48174
B49 42500 Winchester Rd. Temecula California 92590
B56 190 Medline Drive, Suite 200. Richmond Hill Georgia 31324
B66 2700 E. Imperial Highway Lynwood California 90262
B80 2341 Lauwiliwili St, Suite 107 Kapolei Hawaii 96707
B82 9103 Riverside Parkway Lithia Springs Georgia 30122
C02 2200 Cornerstone Parkway. Grayslake Illinois 60030
C03 1500 Medline Pl. McDonough Georgia 30253
C05 1062 Old Dixie Highway. Auburndale Florida 33823
C09 1960 W Miro Way. Rialto California 92376
C32 29895 US Hwy 90 Bus. Katy Texas 77494
C37 5000 Premier Parkway. St. Peters Missouri 63376
C40 81 Campanelli Dr. Uxbridge Massachusetts 01569
C41 1040 Enterprise Parkway South. West Jefferson Ohio 43162
C42 3446 Highway 51 N. Southaven Mississippi 38672
C46 5701 Promontory Parkway, Suite 100 Tracy California 95377
C47 239 Belvidere Rd. Perryville Maryland 21903
C50 8787 W Buckeye Ave. Tolleson Arizona 85353
C54 494 State Route 416. Montgomery New York 12549
C57 5511 W Ten Rd. Mebane North Carolina 27302
C59 2100 Industrial Park Road Hammond Louisiana 70401
C71 264 S 5750 W. Salt Lake City Utah 84104
C75 3770 Hogum Bay Rd NE. Lacey Washington 98516
C89 251 Hilton Dr. Jeffersonville Indiana 47130

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Attachment 6 (cont.)

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ADDITIONAL REMARKS SCHEDULE

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

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

RCH - Hartland, WI 700 W North Shore Dr. Hartland Wisconsin 53029
D46 - Lathrop, CA 18601 Christopher Way Ste 100. Lathrop California 95330
MXC - SPT 16415 Cosmos St. Moreno Valley California 92551
ANGIO 10 Glen Falls Technical Park. Glen Falls New York 12801
E22 600 Derby Ave West Haven Connecticut 06516
E23 3835 John Wall Dr Madison Wisconsin 53704
E26 1390 Sparrows Point Blvd Ste700 Edgemere Maryland 21219
LRD 12001 General Milton Dr. Laredo Texas 78045

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Attachment 4

File Number S030704

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

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

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

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 10TH *day of* DECEMBER *A.D.* 2025 .

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

Authentication #: 2534405556 verifiable until 12/10/2026

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

Alexi Giannoulias

SECRETARY OF STATE

Attachment 3

Medline Industries, LP

FEIN: 36-2596612
An Illinois Limited Partnership

Contact Information:

Three Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Partners:

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

Officers of General Partner - Mozart GP, LLC:

Name	Title	Home Address	SSN	DOB
James M. Boyle	Chief Executive Officer	[redacted]	[redacted]	[redacted]
James M. Pigott	President	[redacted]	[redacted]	[redacted]
Stephen L. Miller	Chief Operating Officer	[redacted]	[redacted]	[redacted]
Michael B. Drazin	Chief Financial Officer	[redacted]	[redacted]	[redacted]
Alexander M. Liberman	General Counsel, Secretary	[redacted]	[redacted]	[redacted]
Lara N. Simmons	Chief Quality Officer*	[redacted]	[redacted]	[redacted]

*Chief Quality Officer - senior executive responsible for overseeing quality management, licensing, and compliance. Note - this role is not an appointed officer.

Attachment 5

DISTRIBUTOR REGISTRATION

194997
~~194996~~

STATE OF MARYLAND
DEPARTMENT OF HEALTH

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Medline Industries, Lp
239 Belvidere Road
Perryville MD 21903

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Medline Industries, Lp
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2027)

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
D07062	05/31/2027

SIGNATURE OF BEARER

194996
194997

State of Maryland

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Medline Industries, Lp
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2027)

SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D07062	05/31/2027

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Distributor Change of Information

A Distributor must report changes in their names, addresses, place of employment or other contact information in order to receive renewal notices, newsletters and other important information. A copy of a legal document, such as a Marriage Certificate, must accompany name changes.

To report changes, submit a completed Change of Information form. The form may be downloaded from the Board's website at http://dhmh.maryland.gov/pharmacy/Pages/ChangeRequest.aspx, or contact the Board to have the form sent to you.

Return the completed form by mail, fax or email to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, Maryland 21203-2051
Toll Free: (800)-542-4964 Fax: (410) 358-6207
Email: dhmh.mdbop@maryland.gov

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

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

Physical Address 239 Belvidere Road

City Perryville State MD Zip 21903

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

City Northfield State IL Zip 60093

Telephone 410-642-2020 Website https://www.medline.com/

Licensing Company Email ralicensing@medline.com

Section 2: Personal Information

First Mark Middle _____ Last Rizzo

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

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

Mailing Address [redacted]

City [redacted] State IL Zip [redacted]

Telephone (410) 642-2020 Email MRizzo@Medline.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
Port Jervis High School			2000-2004	
Address		City	State	Zip
10 US-209		Port Jervis	NY 1	2771
Diploma/Degree obtained, if any				
Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2023-Current	[redacted]	[redacted]	MD	[redacted]
11/2022-07/2023			MD	
08/2018-11/2022			PA	
08/2015-08/2018			PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			09/2022 - Current	
Business Address		City	State	Zip
239 Belvidere Rd		Perryville	MD	21903
Phone	Title		Number of Employed Hours	
(410) 642-2020	Operations Manager		6,448	
Description of Duties				
See Attachment 8				

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			04/2018 - 09/2022	
Business Address		City	State	Zip
494 State Route 416		Montgomery	NY	12549
Phone	Title		Number of Employed Hours	
845-457-5463	Operations Supervisor		8,952	
Description of Duties				
See Attachment 8				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

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

I, Mark Rizzo, **certify that as the MDEG Administrator for**

Medline Industries, LP,

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

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

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

Mark Rizzo
Print Name (First, Last)

Mark R
Original Signature (electronic, copies or stamps not accepted)

12/02/2025
Date

Board Use Only	Date Received: 12/5/25

Attachment 8

[redacted]

MARK V. RIZZO

OBJECTIVE:

To continue a rewarding career in warehousing that continually challenges my abilities and allows for personal and professional growth. A Warehouse professional of eighteen plus years with experience in multi-tasking and implementation of day- to- day operations. Major strengths in employee motivation, training and problem solving. Motivated self-starter who works well as a team player and focuses on time management with attention to detail and the ability to develop and train others.

PROFESSIONAL EXPERIENCE

Medline Industries, Inc. November 2022 - Present

Perryville, MD C47

Operations Manager

- Primarily overseeing all aspects of outbound shipping functions with time spent managing overnight repack and G2P. Main responsibilities include driving key performance metrics through efficient action plans, employee engagement, and enforcing all company policies and procedures

Medline Industries, Inc. 2018 – November 2022

Middletown, NY C54

Operations Supervisor

- First two years supervising outbound for both Medtrans and Parcel/K-Ship with responsibilities including but not limited to managing safety, utilization, and performance of team members, waving work, and handling customer rep concerns over the phone. Also responsible for replenishments, shortage bucket, and scheduling moves
- Spent the next six months overseeing the Housekeeping and Training teams implementing new policies and procedures to hold team members accountable regarding both sanitation and new hire productivity. Focus on engagement in order to improve retention
- Spent last 18 months as the 3am Supervisor of the inbound receiving team in charge of inbound exception, old putaways, cube per master, dock sanitation, FTL, LTL, etc. Focus on improving throughput throughout the department while increasing utilization.

C&S Wholesale Grocers 2010 – 2018

Chester, NY

Shipping Supervisor

- Supervise the day to day shipping operation to ensure areas of responsibility are operating timely and safely
- Help to teach employees the proper execution of warehouse operation practices including safety, quality and sanitation
- Assist the shift managers with creating employee performance development plans. Coach, mentor and guide employees through execution of plans. Progressive coaching and counseling followed as needed while providing continuous feedback
- Identify, Set and Execute Key Performance Indicator's around Safety, Retention, Productivity, Budget and Quality
- Random Audits to encourage a sense of accuracy and ownership in associates
- Investigate and document safety accidents per the company guidelines
- Ensure customer satisfaction is above standard by keeping gate times on target
- Lead supervisor in facilities transition from ELS (Engineered Labor Standard) to Case Pick

C&S Wholesale Grocers 2009 – 2010

Chester, NY

Trainer

- Train and acclimate all new associates safe equipment operation, policies and procedures
- Instruct employees on power equipment while stressing the importance of safety
- Teach new hires to work independently
- Record performance and percentages of new employees
- Help build confidence in new employees to build motivation

C&S Wholesale Grocers 2007 – 2009

Chester, NY

Incentive Selector

- Correctly listen to voice commands and select customer orders to build on a pallet
- Safely move pallets on an electric power jack to fulfill orders, securely wrap pallets with plastic wrap and load them on trailers in order of stops
- Accurately, carefully and efficiently select cases as to not cause shrink losses or damages
- Count items accurately while working at a fast pace
- Maintain clean and safe work environment

EDUCATION

Sussex County Community College 2005 – 2007

Associate Degree – Business Administration

REFERENCES

Furnished Upon Request

Kristy Langston

From: Rosado, Kiara <KRosado@medline.com>
Sent: Wednesday, December 17, 2025 4:22 PM
To: Kristy Langston
Subject: RE: Nevada MDEG Application Medline Industries, LP

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

Hi Kristy,

Thank you for your help!

Statement: Oversee the facility to ensure proper receiving, distribution, storage, shipping and dispensing of prescription drugs and medical devices. Manage multiple team members to ensure proper record keeping, inventory, storage, and product security.

Please let me know if there is anything else I can help clarify.

Thank you,

Kiara Rosado (she/her)
Spec Regulatory Affairs
Quality
Medline Industries, LP
www.medline.com

We make healthcare run better

O:312-209-8883
krosado@medline.com

From: Kristy Langston <klangston@pharmacy.nv.gov>
Sent: Wednesday, December 17, 2025 1:55 PM
To: RA Licensing <RALicensing@medline.com>; Rosado, Kiara <KRosado@medline.com>
Subject: Nevada MDEG Application Medline Industries, LP

CAUTION: This email originated from outside of the organization. Do not click links, open attachments or scan QR codes unless you recognize the sender and know the content is safe.

Hi Kiara,
I am in receipt of the Nevada MDEG application for Medline Industries, LP. Additional information is needed pertaining to the MDG Administrator application. Mark Rizzo's resume covers the logistics/warehousing side of operations, however, per NAC 639.694 we need information specific to his work experience relating to the medical products provide by Medline Industries, LP. Please provide a statement explaining how he meets the 1500 hour minimum working with the products.

4E

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: SleepSafe Drivers, Inc.

MDEG Physical Address: 11300 Strangline Rd

City: Lenexa State: KS Zip: 66215

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855-723-3378 Website: www.sleepsafedrivers.com

Email: Adriank@sleepsafedrivers.com

Name of MDEG Administrator (NAC 639.694): Adrian Knight

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

Kristy Langston

From: Hilary Jordan <HilaryJ@SleepsafeDrivers.com>
Sent: Thursday, January 29, 2026 11:55 AM
To: Kristy Langston
Cc: Adrian Knight; Jessica Blake
Subject: Re: SleepSafe Drivers, Inc - Nevada MDEG application

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

Kristy

Thanks for reaching out to clarify. Page 2 should be non-publicly traded company. Please let me know if you need anything else from us.

Thanks

Hilary Jordan
Senior Vice President, Customer Success
Office: 855-723-3378 ext. 2312
[redacted]
https://sleepsafedrivers.com/

SLEEPSAFE DRIVERS

"We keep the wheels rolling, safely"

The HIPAA Privacy Rule requires covered entities to safeguard certain Protected Health Information (PHI) related to a person's healthcare. Information being sent to you may include PHI, after appropriate consent, acknowledgment, or authorization from the patient or under circumstances that do not require patient authorization. You, the recipient, are obligated to maintain PHI in a safe and secure manner. You may not re-disclose this patient information without additional patient consent or as required by law. Unauthorized re-disclosure or failure to safeguard PHI could subject us, or you, to penalties described in federal (HIPAA) and state law. If you, the reader of this message, are not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, please notify us immediately and destroy the related message. Thanks for your help

---

From: Kristy Langston <klangston@pharmacy.nv.gov>
Sent: Thursday, January 29, 2026 12:42 PM
To: Hilary Jordan <HilaryJ@SleepsafeDrivers.com>
Cc: Adrian Knight <adriank@SleepsafeDrivers.com>; Jessica Blake <jeblake@medbridgegroup.com>
Subject: RE: SleepSafe Drivers, Inc - Nevada MDEG application

Hi Hilary,
I have one clarifying question before I can move this application to an agenda. On page 2 of the application the business type is marked as sole owner, however, on page 4 the section for publicly traded was filled out. Which is correct?

Thank you,

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

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

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

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): MedBridge Acquisition Corp

Corporation/Organization Name: SleepSafe Drivers, Inc.

Mailing Address: 11300 Strangline Rd

City: Lenexa State: KS Zip: 66215

Telephone: 855-723-3378 Email: ADRIANK@SLEEPSAFEDRIVERS.COM

Contact Person Name: ADRIAN KNIGHT

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Adrian Knight

Print Name of Authorized Person Submitting Application

DocuSigned by:
Adrian Knight

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

1/13/2026

Date

Board Use Only	Date Received: 1/20/26	Amount: $500 ck 7141 6/23

CERTIFICATE OF LIABILITY INSURANCE

8/30/2026 | DATE (MM/DD/YYYY) 1/13/2026

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

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

PRODUCER	Lockton Companies, LLC DBA Lockton Insurance Brokers, LLC in CA CA license #0F15767 1185 Avenue of the Americas, Ste. 2010 New York NY 10036 (646) 572-7300	CONTACT NAME:	
		PHONE (A/C, No, Ext):	FAX (A/C, No):
		E-MAIL ADDRESS:	
		INSURER(S) AFFORDING COVERAGE	NAIC #
		INSURER A: Federal Insurance Company	20281
INSURED 1547480	SleepSafe Drivers, Inc. 11300 Strang Line Road Lenexa, KS 66215	INSURER B: Chubb Custom Insurance Company	38989
		INSURER C: ---- SEE ATTACHMENT ----	
		INSURER D:	
		INSURER E:	
		INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 22905313 **REVISION NUMBER:** XXXXXXX

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	N	N	3609-07-78	1/31/2025	8/30/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 8,000,000 $ 8,000,000 $ 10,000 $ 1,000,000 $ 8,000,000 $ Excluded $
	[ ] AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			NOT APPLICABLE			COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $	N	N	5672-67-31	1/31/2025	8/30/2026	EACH OCCURRENCE AGGREGATE $	$ 5,000,000 $ 5,000,000 $ XXXXXXX
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		NOT APPLICABLE			[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ XXXXXXX $ XXXXXXX $ XXXXXXX
B	Healthcare Prof Liab.	N	N	71-83-8013	1/31/2025	8/30/2026	Each Occ: $8,000,000 Agg: $8,000,000 Ded: $10,000	
C	Products Liab.			See Attached	1/31/2025	8/30/2026	See Attached	

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

CERTIFICATE HOLDER

22905313
Evidence of Insurance

CANCELLATION See Attachments

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

AUTHORIZED REPRESENTATIVE

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Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SLEEPSAFEDRIVERS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF JANUARY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4644937 8300

SR# 20260138496

Authentication: 202809659

Date: 01-14-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

MedBridge Acquisition Corp Officers and Board of Directors

MedBridge Acquisition Corp Officers:

Steve Feldman – President

Tony Gonzalez – Chief Operating Officer

Greg McCarthy – Chief Commercial Officer

MedBridge SuperHoldings Board of Directors:

Alan Quasha

Luke McGee

Steve Feldman

Josh Parnes

Gregg Holst

Kansas State Board of Pharmacy

800 SW Jackson St. Suite 1414
Topeka, Kansas 66612-1244
Phone (785) 296-4056
Fax (785) 296-8420

email pharmacy@ks.gov
www.pharmacy.ks.gov

16-126949
ADRIAN KNIGHT
SleepSafeDrivers, Inc.
11300 Strang Line Rd
Lenexa, KS 66215

Schedules

STATE OF KANSAS
STATE BOARD OF PHARMACY

N° 16-126949

DURABLE MEDICAL EQUIPMENT

This registration Must Be Renewed Annually by **June 30th.**

That **SleepSafeDrivers, Inc.**

has complied with the Pharmacy Act of the State of Kansas providing for the registration of ***Durable Medical Equipment*** *within the State of Kansas, and is hereby granted a REGISTRATION as defined in K.S.A 65-1643 of the State of Kansas under the name of*

SleepSafeDrivers, Inc.

at **11300 STRANG LINE RD** **LENEXA** **KANSAS**

from this date until **6/30/2026** *, unless this registration is surrendered, or revoked or suspended by the Kansas State Board of Pharmacy.*

This registration issued **December 24, 2025.**

KANSAS STATE BOARD OF PHARMACY

By _____ Executive Secretary

THIS REGISTRATION MUST BE POSTED IN A CONSIPICUOUS PLACE - NOT TRANSFERABLE
DO NOT DESTROY - Return to Secretary for change in ownership, location or pharmacist in charge

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG SleepSaafe Drivers Inc. MDEG License # (if applicable) _____

Physical Address 11300 Strang Line Rd

City Lenexa State KS Zip 66215

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-723-3378 Website WWW.sleepsafedrivers.com

Licensing Company Email adriank@sleepsafedrivers.com

Section 2: Personal Information

First Adrian Middle Luther Last Knight

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

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

Mailing Address 11300 Strang Line Rd

City Lenexa State KS Zip 66215

Telephone 855-723-3378 Email adriank@sleepsafedrivers.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Bethany Medical Center		08/1990-0981991	
Address	City	State	Zip
	Kansas City	KS	
Diploma/Degree obtained, if any			
CRTT			

School Name		From - To (MM/YY – MM/YY)	
Kansas State University		1985-1988	
Address	City	State	Zip
	Manhattan	KS	
Diploma/Degree obtained, if any			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1997-2020	[redacted]	[redacted]	KS	[redacted]
From - To (MM/YY – MM/YY) 2020-2022			State KS	
From - To (MM/YY – MM/YY) 2022-Current			State KS	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
SleepSafe Drivers			11/2011-Current	
Business Address		**City**	**State**	**Zip**
11300 Strang Line Rd		Lenexa	KS	66215
Phone	**Title**		**Number of Employed Hours**	
855-723-3378	President & CEO		29,120	
Description of Duties				
Run the Company				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/23/2026
Date

I, Adrian Knight, **certify that as the MDEG Administrator for**

SleepSafe Drivers Inc.,

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

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

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

Adrian Knight
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/23/2026
Date

Board Use Only	Date Received:

4F

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Unicare Diagnostics, LLC

MDEG Physical Address: 3271 Grande Vista

City: Newbury Park State: CA Zip: 91320

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 818-850-1247 Website: https://unicarehealth.net/

Email: scott@lafitteandco.com

Name of MDEG Administrator (NAC 639.694): Robert Peltzman

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	■ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	■ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Robert Peltzman
	Telephone: 818-383-4678

Check the Days the Business will be Opened and provide the Hours of Operation				
▣ Mon: 8:30 - 5:00pm	▣ Tue: 8:30 - 5:00pm	▣ Wed: 8:30 - 5:00pm	▣ Thurs: 8:30 - 5:00pm	▣ Fri: 8:30 - 5:00pm
☐ Sat:	☐ Sun:	☐ Holidays: Varies		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(l))
PTAN: 0531100001
MediCal: PHA439640
MediCal: PHA452910

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Unicare Buyer, LLC

Corporation/Organization Name: Unicare Diagnostics, LLC

Mailing Address: 3271 Grande Vista

City: Newbury Park State: CA Zip: 91320

Telephone: 773-562-3739 Email: scott@lafitteandco.com

Contact Person Name: Scott Vold

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Scott Vold

Print Name of Authorized Person Submitting Application

Scott Vold

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

1/14/2026

Date

Board Use Only	Date Received: _____ Amount: _____

Kristy Langston

From: Joshua McCann <jmccann@polsinelli.com>
Sent: Friday, January 16, 2026 3:46 PM
To: Kristy Langston; Mark Armstrong
Cc: Mark I. Sedar
Subject: RE: Nevada Nonresident MDEG Application

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

Hi Kristy,

Confirming that there are no individual owners/shareholders/partners of Unicare Diagnostics, LLC with 10% or greater ownership.

Kind regards,
Josh

Joshua McCann, PharmD
Associate Attorney

jmccann@polsinelli.com
816.360.4289 office
900 W. 48th Place, Suite 900
Kansas City, MO 64112

POLSINELLI

Polsinelli PC, Polsinelli LLP in California
polsinelli.com
polsinellihealthcaresolutions.com

From: Kristy Langston <klangston@pharmacy.nv.gov>
Sent: Friday, January 16, 2026 5:35 PM
To: Mark Armstrong <MArmstrong@Polsinelli.com>
Cc: Mark I. Sedar <msedar@pharmacy.nv.gov>; Joshua McCann <jmccann@polsinelli.com>
Subject: RE: Nevada Nonresident MDEG Application

EXTERNAL EMAIL klangston@pharmacy.nv.gov

Thank you, Mark. I am confirming receipt of the application. Are there any individual owners/shareholders/partners of Unicare Diagnostics, LLC with 10% or greater ownership?

Thank you,

Kristy Langston
Licensing Supervisor
Nevada State Board of Pharmacy
(775) 850-1440
klangston@pharmacy.nv.gov

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 3/13/2025

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

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

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Becca Mullenbach PHONE (A/C, No, Ext): (319) 274-8622 FAX (A/C, No): E-MAIL ADDRESS: Becca.Mullenbach@vgm.com
INSURED: Unicare Diagnostics Inc. Unicare Health Services - BreathRite Pharmacy 3271 Grande Vista Dr Newbury Park CA 91320	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: STATE NATIONAL INSURANCE CO 12831 INSURER B: LIBERTY MUTUAL INSURANCE CO 87060 INSURER C: STATE NATIONAL INSURANCE CO 12831 INSURER D: TECHNOLOGY INSURANCE COMPANY, I 42376 INSURER E: INSURER F:

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR X Professional Liability GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:	X		VGM D1024 G1252-22	03/27/2025	03/27/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
B	AUTOMOBILE LIABILITY ANY AUTO ALL OWNED AUTOS [ ] SCHEDULED AUTOS X HIRED AUTOS [X] NON-OWNED AUTOS			BAS (25) 57012791	08/21/2024	08/21/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
C	[ ] UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION $			VGM UM1024 5364-10	03/27/2025	03/27/2026	EACH OCCURRENCE AGGREGATE	$ 3,000,000 $ 3,000,000
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [ ] N/A If yes, describe under DESCRIPTION OF OPERATIONS below			TWC4482436	09/29/2024	09/29/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000

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

Certificate holder is named additional insured as required by written contract.

CERTIFICATE HOLDER

Fidelity Capital Partners, LLC and or its assigns
19600 Fairchild Rd, Ste 120
Irvine CA 92612

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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Unicare Diagnostics, LLC – List of Officers

1. Scott Vold – CEO, President, Secretary
2. William Code – Vice President
3. Ian Weber – Vice President

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	UNICARE DIAGNOSTICS, LLC
Entity No.:	1621317
Registration Date:	08/11/1988
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of January 13, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 409213428

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 45291

NAME: BREATHERITE PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

3271 GRANDE VISTA
NEWBURY PARK CA 91320
VENTURA COUNTY

ISSUANCE DATE

MAY 29, 2001

EXPIRATION DATE

MAY 1, 2026

CURRENT DATE / TIME

JANUARY 26, 2026
4:32:4 PM

LICENSE RELATIONSHIPS

NAME: PELTZMAN, ROBERT STEVEN

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 25946 **PRIMARY STATUS:** CLEAR

B4281-2929 01/13/2026 9:25 AM Received by California Secretary of State

LLC-1A File #

For Office Use Only

-FILED-

File No.: BA20260090434

Date Filed: 1/13/2026

State of California
Secretary of State

Limited Liability Company
Articles of Organization - Conversion

IMPORTANT — Read all instructions before completing this form. This Space For Filing Use Only

Converted Entity Information

1. Name of Limited Liability Company (The name must include the words Limited Liability Company or the abbreviations LLC or L.L.C. The words Limited and Company may be abbreviated to Ltd. and Co., respectively.)

Unicare Diagnostics, LLC

2. The purpose of the limited liability company is to engage in any lawful act or activity for which a limited liability company may be organized under the California Revised Uniform Limited Liability Company Act.

3. The limited liability company will be managed by (check only one):

☐ One Manager ☐ More Than One Manager ☑ All Limited Liability Company Member(s)

4. Initial Street Address of Limited Liability Company's Designated Office in CA	City	State	Zip Code
3271 Grande Vista Drive, Newbury Park		CA	91320

5. Initial Mailing Address of Limited Liability Company, if different from Item 4	City	State	Zip Code

6. Initial Agent for Service of Process: Item 6a: List the name of an individual or a corporation registered in CA under California Corporations Code section 1505 that agrees to be your agent for service of process. You may not list the converted entity as the agent. Item 6b: If the agent is an individual, list the agent's CA business or residential street address. Item 6c: If the agent is an individual and the converting entity is a CA corporation, limited partnership or general partnership, list the the agent's mailing address. Do not list an address if the agent is a CA registered corporate agent as the address for service of process is already on file.

a. Name of Agent For Service of Process: Darren Friedman

b. If an Individual, Street Address of Agent for Service of Process - *Do not list a P.O. Box*	City	State	Zip Code
3271 Grande Vista Drive	Newbury Park	CA	91320

c. If an Individual, Mailing Address of Agent for Service of Process	City	State	Zip Code
3271 Grande Vista Drive	Newbury Park	CA	91320

Converting Entity Information

7. Name of Converting Entity

Unicare Diagnostics Inc.

8. Form of Entity	9. Jurisdiction	10. CA Secretary of State Entity Number, if any
stock corporation	California	1621317

11. The principal terms of the plan of conversion were approved by a vote of the number of interests or shares of each class that equaled or exceeded the vote required. If a vote was required, the following was required for each class:

The class and number of outstanding interests entitled to vote.	AND	The percentage vote required of each class.
100,000 shares of common stock		100%

Additional Information

12. Additional information set forth on the attached pages, if any, is incorporated herein by this reference and made part of this certificate.

13. I certify under penalty of perjury that the contents of this document are true. I declare I am the person who executed this instrument, which execution is my act and deed.

Darren Friedman

Signature of Authorized Person

Darren Friedman, CEO

Type or Print Name and Title of Authorized Person

Darren Friedman

Signature of Authorized Person

Darren Friedman, Secretary

Type or Print Name and Title of Authorized Person

LLC-1A (REV 12/2024) 2024 California Secretary of State

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG BreatheRite Pharmacy MDEG License # (if applicable) _____

Physical Address 3271 Grande Vista

City Newbury Park State CA Zip 91320

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 818-850-1247 Website https://unicarehealth.net/

Licensing Company Email scott@lafitteandco.com

Section 2: Personal Information

First Darren Middle _____ Last Friedman

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

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

Mailing Address [redacted]

City [redacted] State CA Zip [redacted]

Telephone [redacted] Email darren@unicarehealth.net

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Chatsworth High School		01/79 - 12/82	
Address	**City**	**State**	**Zip**
10027 Lurline Ave	Chatsworth	CA	91311
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/16 - 01/26	[redacted]	[redacted]	CA	[redacted]
01/01 - 05/16			CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Unicare Health Services			10/88 - 01/26
Business Address	**City**	**State**	**Zip**
3271 Grande Vista Drive	Newbury Park	CA	91320
Phone	**Title**	**Number of Employed Hours**	
805-375-0033	CEO - Respiratory Therapist	72,960	
Description of Duties			
Overseeing clinical and management of facility.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

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

I, Darren Friedman, **certify that as the MDEG Administrator for**

Unicare Diagnostics, LLC,

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

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

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

Darren Friedman

Print Name (First, Last)

Darren Friedman

Original Signature (electronic, copies or stamps not accepted)

1/9/2026

Date

Board Use Only	Date Received:

4G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Cogent Biosciences, Inc.

Physical Address: 275 Wyman Street, 3rd Floor

City: Waltham State: MA Zip: 02451

Mailing Address (if different from physical address): 275 Wyman Street, 3rd Floor

City: Waltham State: Massachusetts Zip: 02451

Telephone: 617-945-5576 Website: https://www.cogentbio.com/

Name of Designated Representative (DR): Elodie Rosinovsky

Licensing Company Email: Statelicensure@cogentbio.com DR Email: elodie.rosinovsky@cogentbio.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies/ Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

LDL

Original Signature (electronic, copies or stamps not accepted)

12-15-2025

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: zero

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Cogent Biosciences, Inc.

Corporation Name: Cogent Biosciences, Inc.

Mailing Address: 275 Wyman Street, 3rd Floor

City: Waltham State: Massachusetts Zip: 02451

Telephone: 617-945-5576 Email: Statelicensure@cogentbio.com

Contact Person Name: Elodie Rosinovsky

Date of SEC Registration: 3/30/2018	SEC Registration Number: 0001622229	Stock Exchange Symbol: COGT

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Cogent Biosciences, Inc.
Facility Name

Evan Kearns
Print Name of Authorized Person Submitting Application

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

12-15-2025
Date

Board Use Only	Date Received: 1/12/26	Amount: $1000 CK 5030

Description of Operations

Cogent Biosciences, Inc. is a Virtual Manufacturer based in Massachusetts. Cogent's products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors and Specialty Pharmacies by a Third-Party Logistics Provider who is licensed to ship pharmaceutical products into your state. Cogent Biosciences, Inc. is publicly traded on the NASDAQ (COGT). Cogent was incorporated in the State of Delaware on 3/10/2014.

Contract Manufacturer Information:
Cogent will be using the contract manufacturer and packager below to produce our product:

Hovione FarmaCiencia, S.A
Quinta Sao Pedro
Loures, 2674-506, Portugal
FEIN: 3002807208

A+ Secure Packaging dba Cardinal Health Packaging Solutions
339 Mason Road
La Vergne, TN 37086
FEIN: 3008816891

At no time does Cogent's Contract Manufacturer own the product, contract with Cogent's customers, invoice, nor sell Cogent's product. Cogent's products are not Controlled Substances.

Labeler Code:

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Solutions, LLC ("ICS") acts as Cogent's Third-Party Logistics (3PL) provider to manage the storage and distribution of product to Specialty Distributors and Specialty Pharmacies throughout the United States.

Integrated Commercialization Solutions, LLC
420 International Blvd., Suite 500
Brooks, KY 40109

Cogent's hours of operation are 8:00 am – 5:00pm EST Monday through Friday.

OWNERSHIP

Cogent Biosciences, Inc. is a publicly traded virtual manufacturer of pharmaceutical products located in Waltham, MA. Cogent is incorporated in the state of Delaware.

COMPANY INFORMATION

Cogent Biosciences, Inc.
275 Wyman Street, 3rd Floor
Waltham, MA 02451
Phone: 617-945-5576
statelicensure@cogentbio.com

CORPORATE OFFICERS

Andrew Robbins, Chief Executive Officer
275 Wyman Street, 3rd Floor
Waltham, MA 02451

John Green, Chief Financial Officer
275 Wyman Street, 3rd Floor
Waltham, MA 02451

John Robinson, Chief Scientific Officer
275 Wyman Street, 3rd Floor
Waltham, MA 02451

Jessica Sachs, Chief Medical Officer
275 Wyman Street, 3rd Floor
Waltham, MA 02451

Cole Pinnow, Chief Commercial Officer
275 Wyman Street, 3rd Floor
Waltham, MA 02451

Evan Kearns, Chief Legal officer and Corporate Secretary
275 Wyman Street, 3rd Floor
Waltham, MA 02451

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COGENT BIOSCIENCES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF APRIL, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "COGENT BIOSCIENCES, INC." WAS INCORPORATED ON THE TENTH DAY OF MARCH, A.D. 2014.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

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SR# 20251619114

Authentication: 203466568

Date: 04-17-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Cogent Biosciences, Inc.
275 Wyman Street, 3rd Floor
Waltham, MA 02451

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200143

Type: Virtual Manufacturer

Issue Date: 11/26/2025

Expiration Date: 11/26/2026

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

Last name, First name	Location	Job Title
Amatucci, Dante	Waltham, Massachusetts	Staff Accountant
Armstrong, William	Waltham, Massachusetts	Senior Director, Financial Planning and Analysis
Barrett, Jamie	Waltham, Massachusetts	Associate Director, Clinical Operations
Burdick, Susan	Waltham, Massachusetts	Senior Contracts Manager
Clark, Megan	Waltham, Massachusetts	Vice President, Controller
Diyewar, Ayushree	Waltham, Massachusetts	Clinical Trial Associate
Escobar, Meghan	Waltham, Massachusetts	Manager, People Operations
Escudero, Diana	Waltham, Massachusetts	Clinical Trial Manager
Exter, Ben	Waltham, Massachusetts	Senior Vice President, Head of Regulatory and Pharmacovigilance
Faller, William	Waltham, Massachusetts	Senior Desktop Engineer
Fang, Fang	Waltham, Massachusetts	Vice President, Biometrics
Garon, Jennifer	Waltham, Massachusetts	Compliance Director
Green, John	Waltham, Massachusetts	Chief Financial Officer
Guo, Peng	Waltham, Massachusetts	Director, Quantitative Clinical Pharmacology
Hamilton, Alla	Waltham, Massachusetts	Director, Medical Writing
Haria, Bhumi	Waltham, Massachusetts	Patient Recruitment and Site Engagement Associate
Harkin, Dana	Waltham, Massachusetts	Executive Director, Patient Recruitment and Site Engagement
Harvey, Jessica	Waltham, Massachusetts	Director, People Partner
Hoda, Sarina	Waltham, Massachusetts	Senior Director, Total Rewards
Honig, Emily	Waltham, Massachusetts	Senior Counsel, Commercial and Healthcare Compliance
Idris, Idris	Waltham, Massachusetts	Senior Network Systems Administrator
Kearns, Evan	Waltham, Massachusetts	Chief Legal Officer
Kim, Eiu	Waltham, Massachusetts	Vice President, IT
Kim, Joanna	Waltham, Massachusetts	Senior Director, Commercial Operations and Analytics
LaHaie, Celeste	Waltham, Massachusetts	Senior Clinical Scientist
Lehr, Philinia	Waltham, Massachusetts	Director, Patient Recruitment & Site Engagement
Mammen, Pradeep	Waltham, Massachusetts	Executive Director, Patient Services
Mejia, Melissa	Waltham, Massachusetts	Senior Clinical Trial Manager
Mohamed, Kevin	Waltham, Massachusetts	Vice President, Global Commercial Operations and Analytics
Moyers, Zachary	Waltham, Massachusetts	Senior Clinical Trial Manager
Moynihan, Kevin	Waltham, Massachusetts	Director, Clinical Operations
Pilla, Amanda	Waltham, Massachusetts	Senior Director, Clinical Development Operations
Pray, Meryll	Waltham, Massachusetts	Director, Program Management
Prolman, Sera	Waltham, Massachusetts	Senior Manager, Accounting
Raye, Kristil	Waltham, Massachusetts	Senior Payroll Specialist
Rosinovsky, Elodie	Waltham, Massachusetts	Senior Vice President, CMC & Supply Chain
Ruffy, Lisa	Waltham, Massachusetts	Executive Director, Pharmacovigilance and Risk Management
Sachs, Jessica	Waltham, Massachusetts	Chief Medical Officer
Schellhammer, Erin	Waltham, Massachusetts	Chief People Officer
Scuzzarella, Janey	Waltham, Massachusetts	Clinical Trial Manager
Seigars, Kate	Waltham, Massachusetts	Director, CMC Project Management
Sethuraman, Sethukkarasi	Waltham, Massachusetts	Accounts Payable Specialist
Shah, Nisha	Waltham, Massachusetts	Senior Director, Pharmacovigilance
Soomre, Amanda	Waltham, Massachusetts	Clinical Trial Manager

Spatz, Anne	Waltham, Massachusetts	Office Coordinator/ Administrative Assistant
Sun, Lei	Waltham, Massachusetts	Vice President, Clinical Pharmacology & Translational Medicine
Swenson, Christine	Waltham, Massachusetts	Executive Strategic Regulatory Advisor
Tarani, Danielle	Waltham, Massachusetts	Senior Executive Assistant to the CEO
Tramonte, Alexandria	Waltham, Massachusetts	Manager, Accounting Operations
Villemaire, Haylee	Waltham, Massachusetts	Clinical Trial Manager
Waarich, Hannah	Waltham, Massachusetts	Senior Director, Investor Relations
Wang, Yimei	Waltham, Massachusetts	Senior Director, Statistical Programming
Watson, Courtney	Waltham, Massachusetts	Senior Vice President, Head of Clinical Development Operations
Wilson, Erin	Waltham, Massachusetts	Senior Manager, Formulation
Zbitnoff, Sasha	Waltham, Massachusetts	Senior Director, Program Management - Late Stage Development
Zou, Liangxing	Waltham, Massachusetts	Director, Biostatistics
Zsolnay, Lilo	Waltham, Massachusetts	Director, Commercial Operations and Analytics

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to

Commission file number: 001-38443

COGENT BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**46-5308248**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
275 Wyman Street, 3rd Floor Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

(617) 945-5576
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.001 Par Value	**COGT**	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $869.3 million (based on the last reported sale price on the Nasdaq Global Select Market as of such date).

As of February 21, 2025, there were 113,850,090 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated herein by reference from our definitive proxy statement relating to the 2025 Annual Meeting of Stockholders, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the annual period to which this report relates.

Cogent Biosciences, Inc.
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Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- Our business is highly dependent on the success of our bezuclastinib program and our ability to discover and develop additional product candidates. We may not be successful in our efforts to develop bezuclastinib or expand our pipeline of drug candidates.
- We will require substantial additional funding. If we fail to obtain additional financing when needed, or on attractive terms, we may be unable to complete the development and commercialization of our product candidates.
- If unacceptable side effects are identified during the development of our drug candidates, we may need to abandon or limit such development.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue potential and ability to achieve profitability will be adversely affected.
- Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, may be interpreted differently if additional data are disclosed, and are subject to audit and verification procedures that could result in material changes in the final data.
- Regulatory authorities, including the U.S. Food and Drug Administration ("FDA"), may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.
- We currently rely and for the foreseeable future will continue to rely on third parties to conduct our clinical trials and to assist with various research, discovery, manufacturing and supply activities. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates or discover new product candidates.
- The third parties upon whom we rely for the supply of the API and drug product used in bezuclastinib are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- The price of our stock may be volatile, and you could lose all or part of your investment.

The summary risk factors described above should be read together with the text of the full risk factors in Item 1A. "Risk Factors" and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy and plans, and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "should," "expects," "might," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," "seek," "would" or "continue," or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Some of the key factors that could cause actual results to differ from our expectations include:

- the potential impacts of raising additional capital, including dilution to our existing stockholders, restrictions on our operations or requirements that we relinquish rights to our technologies or product candidates;
- the success, cost, and duration of our product development activities and clinical trials, including the enrollment rates in our clinical trials;
- the timing of our planned regulatory submissions to the FDA for our bezuclastinib product candidate and any other product candidates we may develop;
- our ability to obtain and maintain regulatory approval for our bezuclastinib product candidate and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- the potential for our identified research priorities to advance our bezuclastinib product candidate or for our teams to discover and develop additional product candidates;
- the ability to license additional intellectual property rights relating to our bezuclastinib product candidate or future product candidates from third-parties and to comply with our existing or future license agreements and/or collaboration agreements;
- our ability to commercialize our bezuclastinib product candidate and future product candidates in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further discovery, development and commercialization of our existing and future product candidates;
- the scalability and commercial viability of our manufacturing methods and processes;
- the commercialization of our product candidates, if approved;
- our ability to attract collaborators with development, regulatory, and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- the pricing and reimbursement of our product candidates, if approved;

- regulatory developments in the United States and foreign countries, including pharmaceutical and biological product marketing regulation;
- the impact of adverse business and economic conditions including inflationary pressures, general economic slowdown or a recession, high interest rates, changes in monetary policy, banking institution instability, changes in trade policies, including tariffs or other trade restrictions or the threat of such actions, and the prospect of a shutdown of the U.S. federal government;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the development and success of competing therapies that are or may be under development in clinical trials or become available commercially;
- our ability to attract and retain key scientific and management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our use of the proceeds from the private placements, sales of our preferred stock and public offerings of our common stock from time to time; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our bezuclastinib product candidate and future product candidates.

While we may elect to update these forward-looking statements at some point in the future, whether as a result of any new information, future events, or otherwise, we have no current intention of doing so except to the extent required by applicable law.

PART I

Unless the context otherwise requires, we use the terms "Cogent," "company," "we," "us," and "our" to refer to Cogent Biosciences, Inc. and, where appropriate, our subsidiaries.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company focused on developing precision therapies for genetically defined diseases. Our approach is to design rational precision therapies that treat the underlying cause of disease and improve the lives of patients. Our most advanced program is bezuclastinib, also known as CGT9486, a highly selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. In the vast majority of cases, KIT D816V is responsible for driving Systemic Mastocytosis ("SM"), a serious and rare disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors ("GIST"), a type of cancer with strong dependence on oncogenic KIT signaling. Bezuclastinib is a highly selective and potent KIT inhibitor with the potential to provide a new treatment option for these patient populations. We are developing bezuclastinib to treat patients living with Non-Advanced Systemic Mastocytosis ("Non-AdvSM"), Advanced Systemic Mastocytosis ("AdvSM") and GIST. We also have an ongoing Phase 1 study of our novel internally developed FGFR2 inhibitor, CGT4859. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases initially targeting mutations in ErbB2, PI3Kα and KRAS.

We have assembled a management team with extensive experience in the research, development, manufacturing and commercialization of pharmaceutical products, specifically including numerous successful precision medicines for genetically defined diseases. With the support of our board of directors and their expertise, we believe that the Company is well positioned to develop and commercialize novel precision medicines. Beginning with bezuclastinib, our mission is to develop and commercialize pharmaceutical products that improve the lives of patients fighting rare, genetically driven diseases.

Our Strategy

Our vision is to discover, develop, and commercialize best-in-class therapies that have a meaningful impact for patients with genetically defined diseases. The principal components of our strategy include:

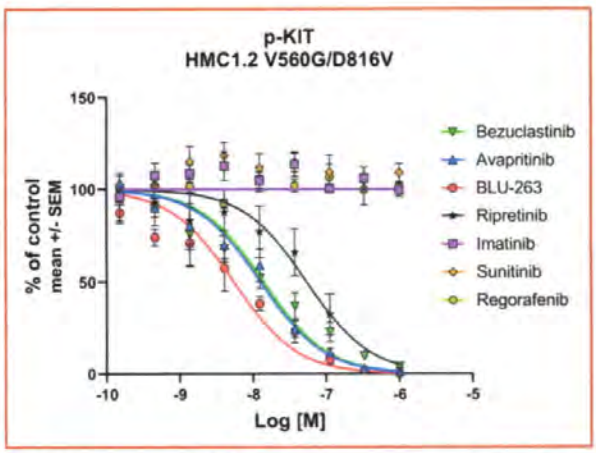
- Explore the clinical utility of bezuclastinib in patients with Non-AdvSM;
- Explore the clinical utility of bezuclastinib in patients with AdvSM;
- Explore the clinical utility of bezuclastinib in combination with sunitinib as a second-line treatment for patients with GIST;
- Prepare to commercialize bezuclastinib should any or all of our active clinical trials demonstrate clinical benefit for patients with high unmet medical need;
- Explore the clinical utility of CGT4859, a reversible, selective FGFR2 inhibitor in patients with documented FGFR mutations, including advanced cholangiocarcinoma;
- Advance our ErbB2, PI3Kα and KRAS preclinical programs, as well as our other undisclosed preclinical programs; and
- Discover and develop additional precision medicines for patients with genetically defined diseases.

Our Pipeline



Bezuclastinib Overview

Bezuclastinib is designed to target mutations within the KIT receptor tyrosine kinase, including KIT D816V. As a Type I inhibitor, bezuclastinib is designed to selectively bind the active conformation of mutant KIT. In preclinical studies, bezuclastinib has demonstrated comparable potency relative to other FDA-approved KIT mutant inhibitors, and clear selectivity for KIT mutations versus other kinase targets frequently associated with other KIT inhibitors including, but not limited to PDGFRα, PDGFRβ, VEGFR2, FLT3, CSF1R and KDR. In preclinical studies of bezuclastinib, limited blood-brain-barrier penetration was observed, and there have been no clinically significant CNS toxicities identified. This preclinical profile of selectivity against kinases that have been associated with off-target toxicities and limited blood-brain-barrier penetration differentiate bezuclastinib from other KIT mutant inhibitors, and support the potential for a best-in-class clinical profile. The figures below provide a summary of potency and selectivity preclinical data.



HMC1.2 human mast cells (V560G/D816V) were treated with inhibitors for 1 hour followed by analysis for phosphorylated c-KIT ELISA (R&D Systems)

Compound	Cell IC_{50} (nM)
	KIT V560G/D816V (HMC 1.2)
Bezuclastinib	**14**
Avapritinib	13
BLU-263	6
Ripretinib	54
Imatinib	>1000
Sunitinib	>1000
Regorafenib	>1000

IC_{50} values from ELISA in (A) in nM are represented for bezuclastinib and other KIT inhibitors

Figure 1. Potent Inhibitor of KIT Activation Loop Mutants, Including D816V (Source: AACR 2022)

Compound	KIT D816V (HMC 1.2)	WT KIT	PDGFRα	PDGFRβ	CSF1R	FLT3	KDR
Bezuclastinib	14	121	> 10,000	> 10,000	> 10,000	> 1000	> 1000
Avapritinib	13	114	53	10	249	305	> 1000
BLU-263	6	355	21	6	161	345	> 1000

Figure 2. Selectivity Against Related Kinases (Source: AACR 2022)

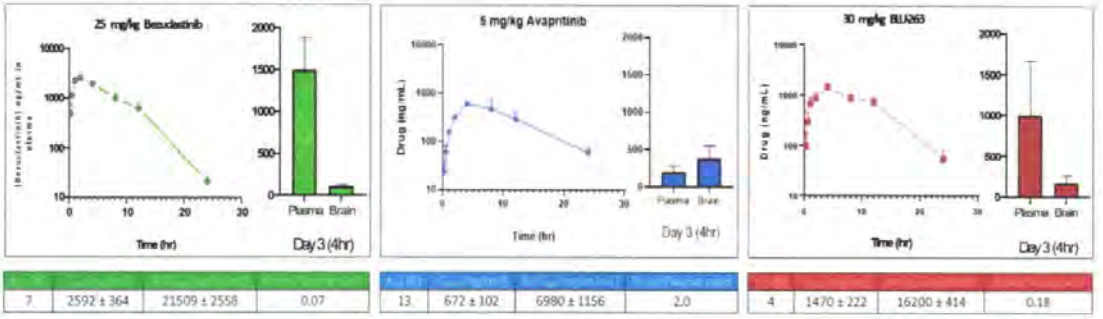


Figure 3. Bezuclastinib Demonstrates Minimal Brain Penetration (Source: AACR 2022)

We licensed the exclusive worldwide rights to develop and commercialize bezuclastinib from Plexxikon Inc., a Daiichi Sankyo subsidiary ("Plexxikon"). Under the terms of the license agreement, Plexxikon received an upfront payment and is eligible for additional development and regulatory milestone payments along with mid- to high- single-digit royalty payments.

Clinical Trials and Disease Overviews

Bezuclastinib – SM

SM is driven by KIT D816V mutations causing a perpetual 'on' state within mast cells, a type of white blood cell, leading to proliferation and accumulation in various internal organs and bone marrow. Key biomarkers of SM include but are not limited to, elevated serum tryptase, high mass cell burden in bone marrow and the KIT D816V variant allele frequency. As a highly selective and potent KIT inhibitor, bezuclastinib has the potential to provide a new treatment option for patients with SM. SM occurs when mast cells inappropriately accumulate in various internal organs in the body. Approximately 90% of SM patients present with Non-AdvSM and 10% of patients present with AdvSM, a rare and very aggressive form of SM. There are three subtypes of AdvSM: aggressive SM ("ASM"), SM with associated hematologic neoplasm ("SM-AHN") and mast cell leukemia ("MCL").

Patients diagnosed with Non-AdvSM experience a life-long illness with chronic symptoms including headaches, urticaria pigmentosa, skin lesions, skin redness and warmth (flushing), abdominal pain, bloating, vomiting, diarrhea, and gastroesophageal reflux ("GERD"), that significantly impact the patient's quality of life. Many patients are also at high risk for severe, life-threatening anaphylactic reactions to various triggers such as insect bites or stings. Patients with Non-AdvSM suffer from a poor quality of life and are in need of new treatment options.

Patients with AdvSM may suffer from a multitude of debilitating symptoms such as anemia, thrombocytopenia, ascites, bone fractures, gastrointestinal abnormalities, and enlargement of the liver, spleen, and lymph nodes, which ultimately lead to organ failure and early death. Patients with AdvSM have a significantly diminished lifespan with a median survival of less than 3.5 years.

Based on the characteristics of bezuclastinib, we are pursuing development of the compound in both patients living with AdvSM and patients with Non-AdvSM, the vast majority of whom have a KIT D816V mutation. Emerging clinical data for other kinase inhibitors with activity against KIT D816V have shown that SM patients are highly sensitive to inhibition of the target. Bezuclastinib was specifically designed to selectively inhibit KIT mutations, including KIT D816V.

The underlying SM patient population is not yet well understood. The prevalence of SM in the United States is estimated to be up to 30,000 patients, with the prevalence of Non-AdvSM being approximately 25,000 patients. We believe there is a significant unmet medical need for clinically active, well tolerated treatment options for this patient population. We believe bezuclastinib is well suited to meet this need and target the direct underlying cause of SM. The FDA has granted orphan drug designation to bezuclastinib for the treatment of Mastocytosis.

We expect to report top-line results from our SUMMIT trial in July 2025 and from our APEX trial in the second half of 2025, and we plan to submit the first bezuclastinib New Drug Application ("NDA") by the end of 2025 for patients with SM.

In the first quarter of 2025, we expect to initiate an expanded access program in the United States for SM patients to receive investigational bezuclastinib after meeting certain eligibility criteria.

SUMMIT (Non-AdvSM)

SUMMIT is our registration-directed randomized, global, multicenter, double-blind, placebo-controlled, multi-part Phase 2 clinical trial for patients with Non-AdvSM. The study is designed to explore the safety and efficacy of bezuclastinib in patients with moderate to severe Non-AdvSM, which includes Indolent Systemic Mastocytosis ("ISM"), Smoldering Systemic Mastocytosis ("SSM") and Bone Marrow Mastocytosis. Based on the performance of bezuclastinib's optimized formulation in the PEAK lead-in trial, as well as in a healthy normal volunteer study, the SUMMIT trial protocol was amended to allow for the optimized formulation to be introduced during the Phase 1b dose optimization phase. SUMMIT Part 1 completed enrollment in the third quarter of 2023, including over enrollment at 54 patients across Part 1a and Part 1b. SUMMIT Part 2 completed enrollment in the fourth quarter of 2024, including over enrollment at 179 patients. We expect to report top-line results in July 2025.

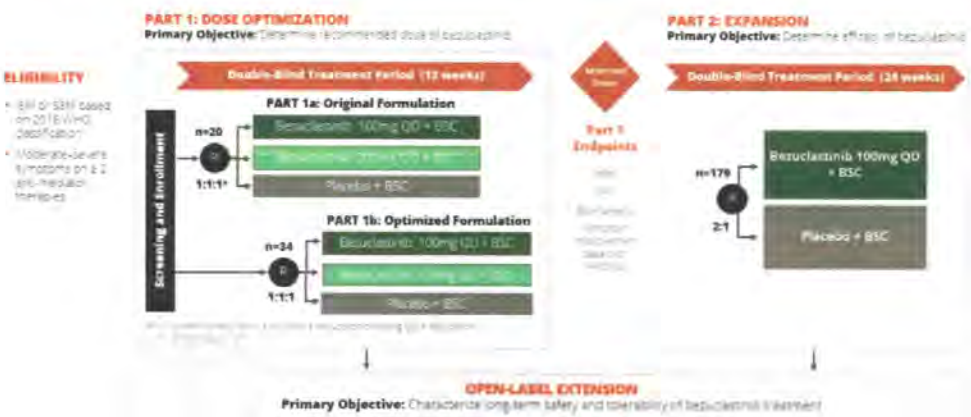


Figure 4. SUMMIT study design graphic

From the data collected in Part 1 of SUMMIT and in accordance with FDA guidelines, we have developed a novel patient reported outcomes measure ("PROM") called Mastocytosis Symptom Severity Daily Diary ("MS2D2"). Based on literature review, patient and physician interviews, data from SUMMIT Part 1 and our interactions with the FDA, we believe our MS2D2 is a reliable, valid and fit-for-purpose PROM. The MS2D2 Total Symptom Score ("TSS") is comprised of 11 items, and scored on a 0-110 scale. The primary endpoint of SUMMIT Part 2 is a comparison of week 24 mean absolute change from baseline in MS2D2 TSS between bezuclastinib and placebo. In June 2024, we announced a positive discussion with the FDA and that we reached alignment with the FDA on the use of MS2D2 in Part 2 of SUMMIT.



Figure 5. Mastocytosis Symptom Severity Daily Diary ("MS2D2") Total Symptom Score

In February 2024, we presented data from SUMMIT Part 1b at the 2024 American Academy of Allergy, Asthma and Immunology. Thirty-four patients were enrolled in Part 1b and were treated with either bezuclastinib or placebo plus best supportive care. These patients were evaluated for signs of clinical activity over 12 weeks, including well-accepted biomarkers of disease burden. Based on the totality of the results from SUMMIT Part 1, the data support 100 mg QD as the optimal dose of bezuclastinib in Part 2 of SUMMIT for patients with Non-AdvSM. After the initial 12-week period, all patients were given the opportunity to receive bezuclastinib in the SUMMIT Open Label Extension ("OLE"). In December 2024 at the 2024 American Society of Hematology ("ASH") Annual Meeting, we presented updated data on the 27 patients who were randomized in either Part 1 or the OLE to receive the 100 mg QD dose.

At the 100 mg QD dose and as of the cut-off date of August 29, 2024, 89% of patients had >50% decrease in serum tryptase by four weeks of treatment with bezuclastinib and 95% of patients with elevated baseline tryptase achieved serum tryptase levels <20 ng/ml by week 24. Additionally, 84% of patients with baseline serum tryptase >11.4ng/ml achieved <11.4ng/mL by week 24.



Figure 6. Mean Percent Change from Baseline in Serum Tryptase in Pooled[a] Patients Receiving 100mg Bezuclastinib
a Includes all patients who received bezuclastinib 100mg QD during Part 1 or OLE. Change from baseline is taken during 24 weeks of active therapy. bn=24, 25, or 26 at some timepoints 26 D

After 24 weeks of active treatment, the 27 patients randomized to receive 100 mg QD were evaluated for signs of clinical activity using multiple PRO measures, including the Mastocytosis Symptom Severity Daily Diary ("MS2D2") and the Mastocytosis Quality-of-Life ("MC-QoL") scale. These patients reported at 56% mean improvement in TSS from baseline.

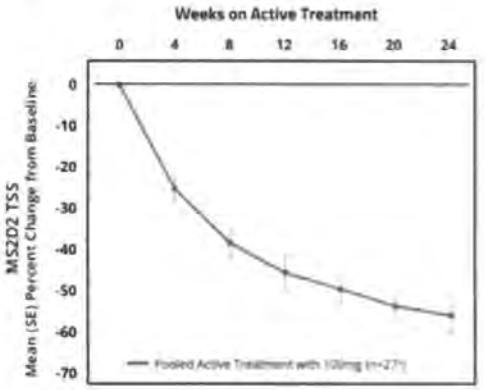


Figure 7. Mean Percent Change from Baseline in MS2D2 Total Symptom Score Over Time in Pooled[a] Patients Receiving 100mg Bezuclastinib
a Includes all patients who received bezuclastinib 100mg QD during Part 1 or OLE. Change from baseline is taken during 24 weeks of active therapy. bn=24, 25, or 26 at some timepoints 26 D

Additionally, 76% of patients demonstrated >50% reduction from baseline in MS2D2 TSS with 88% of patients exceeding 30% reduction from baseline after 24 weeks. At 24 weeks of treatment 31% of patients have already reduced or discontinued best supportive care medications.

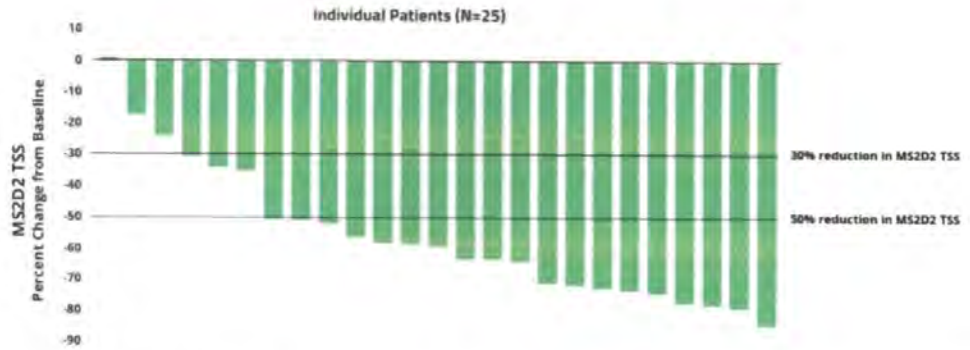


Figure 8. Percent Change from Baseline in MS2D2 Total Symptom Score after 24 Weeks Active Treatment in Individual Patients Receiving 100mg Bezuclastinib

These same patients saw a 49% mean improvement in MC-QOL Total Score at 24 weeks.

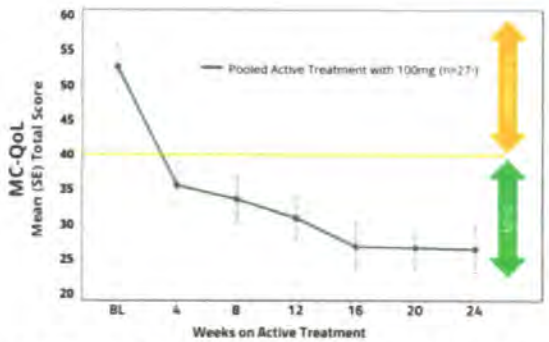


Figure 9. Mean Total Score in MC-QoL, a Quality-of-Life Measure[a], in Pooled[b] Patients Receiving 100mg Bezuclastinib
a MC-QoL is a disease-specific HRQoL questionnaire with 27 items in 4 domains. Total score is linearly transformed to a 0-100 scale
b Includes patients who received bezuclastinib 100mg QD through 24 weeks of active treatment.
c N=23-25 depending on timepoint.

As of the data cutoff, August 29, 2024, the median duration of bezuclastinib treatment was 56 weeks for patients in the active arm and 40 weeks for placebo patients who crossed over to the OLE. The majority of treatment emergent adverse events were low grade and reversible with no treatment-related bleeding or cognitive impairment events reported. The most common treatment-emergent adverse events were hair color changes and transaminase elevations. All patients experiencing elevated transaminases were asymptomatic and reversible: five patients resolved without any dose modifications and remained on study; two patients resolved with dose reduction and remained on study, one of whom re-escalated to the original dose; and two patients resolved following discontinuation. All of the safety data were previously reported at ASH 2024. There were no other discontinuations due to adverse events.

Double-blind + Open-Label Extension 100mg		
Preferred Term	Total Active* (n=27)	
	Gr1/2	Gr3
Hair color changes	21	-
ALT/AST increased	6	3
Nausea	7	
URTI	7	
Diarrhea	6	
Headache	6	
Pruritus	5	
Arthralgia	5	
GERD	5	
Peripheral edema	4	
Alopecia	4	

*Among the nine patients randomized to placebo, only TEAEs that occurred after crossover to bezuclastinib treatment are included.

Figure 10. All Cause Treatment-Emergent Adverse Events (TEAE) ≥ 15 %

APEX (AdvSM)

APEX is our registration-directed global, open-label, multi-center, Phase 2 clinical trial in patients with AdvSM evaluating the safety, efficacy, pharmacokinetic, and pharmacodynamic profiles of bezuclastinib. In April 2023, we initiated Part 2 of the APEX trial using the optimized formulation of bezuclastinib at 150 mg daily dose. An additional APEX cohort was initiated in the third quarter of 2023 and is designed to allow concomitant administration of bezuclastinib with azacitadine in patients with SM-AHN. We completed enrollment in APEX Part 2 in the first quarter of 2025 with 58 patients and expect to present top-line results in the second half of 2025.

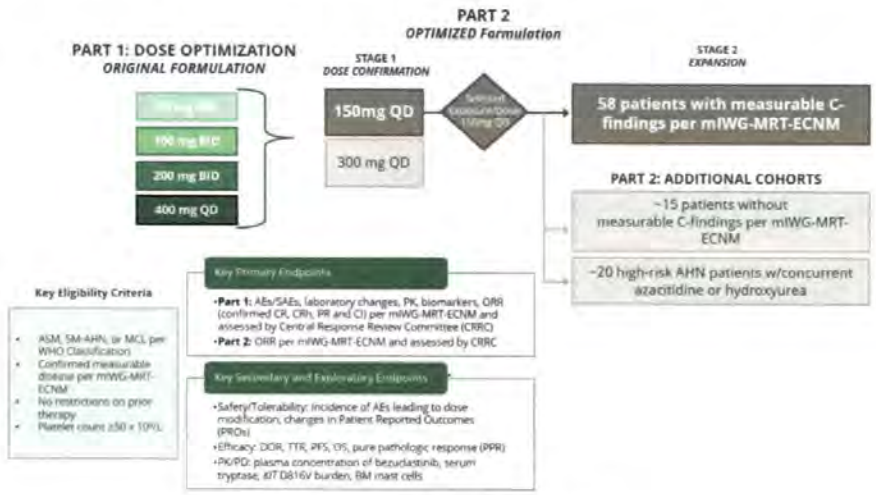


Figure 11. APEX study design graphic

In December 2024, at the 2024 ASH meeting, we reported updated positive clinical data from Part 1 of the APEX trial. Thirty-two patients were treated in Part 1 at one of four dose levels (50 mg BID, 100 mg BID, 200 mg BID or 400 mg QD). In 2024, we announced APEX Part 2 would be conducted at the optimized 150mg QD dose, which closely matches the exposure from 100 mg BID dose in APEX Part 1. Patients were enrolled with the following sub-types: seven patients with ASM, 23 patients with SM-AHN, and two patients with MCL.

As of the cutoff date of October 11, 2024, 32 patients enrolled were evaluated for signs of clinical activity, 27 of whom were mIWG-MRT-ECNM evaluable. An objective response rate ("ORR") of 52% (including complete remission ("CR"), CR with partial hematologic remission ("CRh"), partial remission ("PR"), and clinical improvement ("CI")) was achieved, including 61% ORR for TKI-treatment-naïve patients. An ORR of 88% was achieved by pure pathological response ("PPR") criteria. The median time to achieve response was 2.2 months and median duration of response has not yet been reached. Median progression-free survival ("PFS") was not yet reached at median follow-up of 20 months and the PFS rate at 24 months was 82%.

Best Response, n (%)[Ω]	Confirmed mIWG-MRT-ECNM Responses per CRRC		
	All	TKI[‡] Therapy Naïve	Prior TKI[‡] Exposure
	N=27	N=18	N=9
Overall response rate			
CR + CRh + PR + CI[†]	14 (52)	11 (61)	3 (33)
CR + CRh + PR	13 (48)	10 (56)	3 (33)
Complete Response (CR + CRh)	7 (26)	7 (39)	0
Partial Response (PR)	6 (22)	3 (17)	3 (33)
Clinical Improvement (CI)	1 (4)	1 (6)	0
Stable Disease (SD)	10 (37)	6 (33)	4 (44)
Not evaluable	3 (11)	1 (6)	2 (22)

Best PPR[Ω] Response, n (%)	All
	N=32
Overall response rate (CR + PR)	28 (88)
Complete Response (CR/CRh)	14 (44)
Partial Response (PR)	14 (44)
Stable Disease (SD)	1 (3)
Not Evaluable	3 (9)

Figure 12. Part 1 Responses Observed by mIWG-MRT-ECNM and PPR Criteria (Source: ASH conference 2024)

Ω 5 patients without measurable C-finding at baseline were excluded for being non-evaluable per mIWG-MRT-ECNM criteria; one additional patient was excluded due to discontinuation prior to first dose (not dosed [ND]).

‡ SM-directed therapy with midostaurin only (n=4) or midostaurin and avapritinib (n=5)

† Primary endpoint of Apex study

As of October 11, 2024, 94% of patients achieved a ≥ 50% reduction in serum tryptase levels, with 100% of patients receiving at least two cycles of treatment achieving a ≥ 50% reduction and 66% of patients achieved a reduction of serum tryptase below 20 ng/ml. Additionally, 93% of KIT D9816V-positive patients achieved a ≥ 50% reduction in KIT D816V VAF and 100% of evaluable patients achieved ≥ 50% reduction in bone marrow mast cell burden, with 83% of patients achieving a complete clearance of mast cell aggregates.

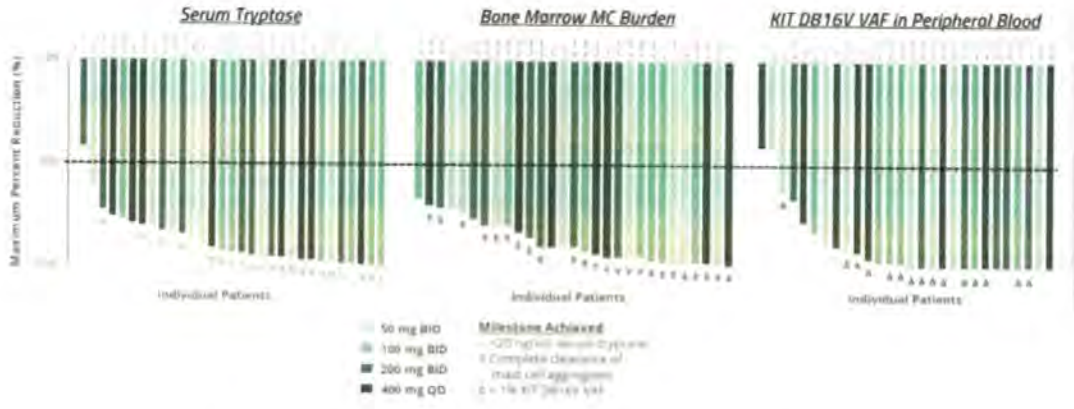


Figure 13. Reductions in markers of mast cell burden (Source: ASH conference 2024)

As of the data cutoff date of October 11, 2024, bezuclastinib continues to demonstrate a differentiated safety and tolerability profile across doses. The majority of hematological adverse events were low grade and reversible. There have been no new treatment-related serious adverse events or discontinuations reported since the 2023 ASH annual meeting. Twelve patients required dose reduction, eight of whom were treated at a 400 mg daily dose.

Bezuclastinib – GIST

GIST is characterized by uncontrolled cell growth in the interstitial cells of the gastrointestinal ("GI") tract. At diagnosis, about 80% of GIST patients' tumors are the result of primary KIT mutations. Imatinib is the current standard of care for treating GIST patients in the first line setting, with a median PFS of 19 months. However, the majority of GIST patients eventually develop resistance to imatinib due to secondary KIT mutations, most notably in exon 17 and exon 13. There are an estimated 2,000 to 3,500 patients with imatinib-resistant GIST eligible for treatment each year in the United States. We believe there is a significant unmet medical need for clinically active, well tolerated treatment options for this patient population and results from our clinical trial of bezuclastinib in combination with sunitinib demonstrated the potential for this novel combination to address the underlying drivers of imatinib resistance. Bezuclastinib has been granted orphan drug designation for the treatment of GIST by the FDA and under the Orphan Drug Act and the European Medicines Agency ("EMA").

Bezuclastinib is designed to be a potent and selective inhibitor of KIT exon 17 mutations. By combining bezuclastinib with sunitinib, a tyrosine kinase inhibitor known to inhibit KIT exon 13 mutations, we believe this combination has the potential to offer a new, active treatment option for imatinib resistant GIST patients.

The safety profile of bezuclastinib was clinically evaluated in approximately 50 GIST patients both as a single agent and as part of a combination therapy. Clinical data from this trial were published in the Journal of American Medical Association ("JAMA") and were presented at several scientific conferences, including by us at the 2020 annual Connective Tissue Oncology Society ("CTOS") meeting, and previously by Plexxikon at the 2018 annual American Society of Clinical Oncology ("ASCO") meeting and the 2017 annual CTOS meeting. In November 2020, we presented final results from a Phase 1/2 trial testing the combination of bezuclastinib with sunitinib in 18 heavily pre-treated GIST patients at 2020 CTOS. In the subset of 15 patients who had not been previously treated with bezuclastinib as a single-agent, the estimated mPFS reached 12 months, the confirmed ORR was 20% and the clinical benefit rate (CR+PR+SD) was 80%, with 27% of patients remaining on therapy out 27-34 months. Importantly, there were no dose limiting toxicities in the three dose levels tested, and the most common Treatment Emergent Adverse Events that were grade 3 or higher included anemia (5 patients, 27.8%), hypophosphatemia (3 patients, 16.7%), diarrhea, fatigue, hypertension, and lymphopenia (each 2 patients, 11.1%).

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV, 89521

To Whom It May Concern:

On behalf of Cogent Biosciences, Inc., attached is Cogent's application for initial state licensure.

Cogent Biosciences, Inc. is a Virtual Manufacturer based in Massachusetts. Cogent's products are manufactured by a Contract Manufacturer and will be distributed to specialty distributors and specialty pharmacies by a Third-Party Logistics Provider who is licensed to ship pharmaceutical products into your state. Cogent Biosciences, Inc. is publicly traded on the NASDAQ (COGT). Cogent was incorporated in the State of Delaware on 3/10/2014.

I hope this narrative is helpful as you review Cogent's application. If you have a question regarding this application, please contact me via email at erin.stewart@twolabs.com.

Thank you in advance for your consideration.

Erin Stewart
Licensing Analyst
Two Labs Pharma Services

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: MIMEDX GROUP, INC.

Physical Address: 1775 West Oak Commons Court, NE

City: Marietta State: GA Zip: 30062

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (888) 543-1917 Website: https://www.mimedx.com/

Name of Designated Representative (DR): Pedro L. Melendez Ruiz

Licensing Company Email: globalregulatory@mimedx.com DR Email: pmelendez@mimedx.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Private Label Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Collagen Matrix, Inc.
Address: 15 Thornton Road City: Oakland State: NJ Zip: 07438
Name: RegenLab USA, LLC
Address: 95 Greene St. City: Jersey City State: NJ Zip: 07302
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Florida
Parent Company (if any): N/A
Corporation Name: MiMedx Group, Inc.
Mailing Address: 1775 West Oak Commons Court, NE
City: Marietta State: GA Zip: 30062
Telephone: (888) 543-1917 Email: globalregulatory@mimedx.com
Contact Person Name: Guilhem Denozière

Date of SEC Registration: 02/28/2008 | SEC Registration Number: 0001376339 | Stock Exchange Symbol: MDXG

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

MIMEDX GROUP, INC.

Facility Name

Ricci S. Whitlow

Print Name of Authorized Person Submitting Application

Ricci S Whitlow

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

10/30/25

Date

Board Use Only	Date Received: 12/17/25	Amount: $1000 CK 663668

MIMEDX

MIMEDX Group, Inc.
Board of Directors and Executive Officers

Board of Directors

M. Kathleen Behrens

Joseph H. Capper

James L. Bierman

Phyllis I. Gardner

Michael J. Giuliani

William A. Hawkins, III

Cato T. Laurencin

K. Todd Newton

Tiffany Olson

Dorothy Puhy

Martin P. Sutter

Executive Officers

Joseph H. Capper
President and Chief Executive Officer
1775 West Oak Commons Ct. NE
Marietta, GA 30062
(770) 651-9106

Douglas Clinton Rice
Executive Vice President, Chief Financial Officer, Chief Accounting Officer and Treasurer
1775 West Oak Commons Ct. NE
Marietta, GA 30062
(770) 651-9137

William F. Hulse IV
Executive Vice President, General Counsel, Chief Administrative and Compliance Officer and Secretary
1775 West Oak Commons Ct. NE
Marietta, GA 30062
(770) 651-9136

Ricci S. Whitlow
Executive Vice President and Chief Operating Officer
1775 West Oak Commons Ct. NE
Marietta, GA 30062
(470) 510-5919

Kimberly Maersk-Moller
Executive Vice President and Chief Commercial Officer
1775 West Oak Commons Ct. NE
Marietta, GA 30062
(470) 591-5235

MIMEDX

MIMEDX Group, Inc.
Significant Entities

Name	Title
John Azeke	Global Dir, Reg Affairs
Janine Best	MGR, Global Reg Affairs
Joseph H. Capper	President and Chief Executive Officer
Guilhem Denozière	AVP, Global Reg Affairs
William F. Hulse IV	Executive Vice President, General Counsel, Chief Administrative and Compliance Officer and Secretary
Camille Kimbro	Specialist, Glb. Reg Aff.
Jeremy Lim	Global Dir, Reg Affairs
Kimberly Maersk-Moller	Executive Vice President and Chief Commercial Officer
Pedro L. Melendez Ruiz	Designated Representative and Sr Dir, Quality Ops
Douglas Clinton Rice	Executive Vice President, Chief Financial Officer, Chief Accounting Officer and Treasurer
Ricci S. Whitlow	Executive Vice President and Chief Operating Officer
Brian Young	VP, Global Reg Affairs

MIMEDX Group, Inc.
Ownership

MiMedx Group, Inc.
1775 West Oak Commons Court, NE
Marietta, GA 30062
FEIN 26-2792552
Publicly Traded Corporation
Percentage Owned: 100%

State of Florida
Department of State

I certify from the records of this office that MIMEDX GROUP, INC. is a corporation organized under the laws of the State of Florida, filed on February 28, 2008.

The document number of this corporation is P08000023430.

I further certify that said corporation has paid all fees due this office through December 31, 2025, that its most recent annual report/uniform business report was filed on April 12, 2025, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifth day of August, 2025



Secretary of State

Tracking Number: 7668644743CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH006148 Status: Active

Mimedx Group Inc

1775 West Oak Commons Court NE
Marietta GA 30062

Expires: 06/30/2027
Issued: 11/17/2025

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Wholesaler Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH006148 Status: Active
Mimedx Group Inc
1775 West Oak Commons Court NE
Marietta GA 30062

Expires: 06/30/2027
Issued: 11/17/2025
Real-time license verification is available at gadch.mylicense.com/verification

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
10/15/2025

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

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

PRODUCER MARSH USA, LLC. 9830 Colonnade Blvd, Suite 410 San Antonio, TX 78230 CN106922293-Full-GAWUP-25-26	**CONTACT NAME:** **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:**
INSURED MIMEDX Group, Inc. 1775 W Oak Commons Ct NE Marrietta, GA 30062	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Starnet Insurance Company — 40045 **INSURER B :** Berkley National Insurance Company — 38911 **INSURER C :** Gemini Insurance Co — 10833 **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** HOU-004147819-04 **REVISION NUMBER:** 1

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			LPK5074608-11	10/15/2025	10/15/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ $ $ $ $ $ $	1,000,000 10,000 1,000,000 3,000,000 Excluded
A	**AUTOMOBILE LIABILITY** ANY AUTO X OWNED AUTOS ONLY X HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			LCA5074324-11	10/15/2025	10/15/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ $ $ $ $	1,000,000
A	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED X RETENTION $ 10,000			LPK5074608-11	10/15/2025	10/15/2026	EACH OCCURRENCE AGGREGATE $	$ $ $	14,000,000 14,000,000
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N N/A If yes, describe under DESCRIPTION OF OPERATIONS below			LWC 5074354-11	10/15/2025	10/15/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	 1,000,000 1,000,000 1,000,000
C	Products Liability Ded: $250K/Event; $1.25M Agg			GL 16666-6	10/15/2025	10/15/2026	Each Claim Aggregate		10,000,000 10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: General evidence of insurance as required by MiMedx customers

CERTIFICATE HOLDER

MiMedx Group, Inc.
1775 W. Oak Commons Ct NE
Marietta, GA 30062

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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AGENCY CUSTOMER ID: CN106922293
LOC #: San Antonio

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA, LLC.	MIMEDX Group, Inc. 1775 W Oak Commons Ct NE Marietta, GA 30062
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

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

Excess Products Liability
Carrier: Illinois Union Insurance Company
Policy #: G47494898 002
Dates: 10/15/2025-10/15/2026
Limits:
$5,000,000 Each Claim
$5,000,000 Term Aggregate

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: MIMEDX GROUP, INC. MDEG License # (if applicable): _____

Physical Address: 1775 West Oak Commons Court, NE

City: Marietta State: GA Zip: 30062

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (888) 543-1917 Website: https://www.mimedx.com/

Licensing Company Email: globalregulatory@mimedx.com

Section 2: Personal Information

First: Pedro Middle: L. Last: Melendez Ruiz

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

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

Mailing Address: [redacted]

City: Homestead State: FL Zip: [redacted]

Telephone: [redacted] Email: pmelendez@mimedx.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Juana Colon High School		Aug 1989 - May 1992	
Address	**City**	**State**	**Zip**
Carr 778 Bda. Pasarell	Comerio	PR	00782
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Puerto Rico Humacao Campus		Aug 1992 - May 1996	
Address	**City**	**State**	**Zip**
Jose E Aguiar Arramburu Carr 908 Km 1.0	Humacao	PR	00792
Diploma/Degree obtained, if any			
BS Physics			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019 to present	[redacted]	Homestead	FL	[redacted]
2005 to 2019		Cidra	PR	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

MIMEDX

July 29, 2025

To Whom It May Concern:

Pedro Melendez, Sr. Director, Quality Operations, is onsite and works at the MIMEDX Group, Inc. facility, 1775 West Oak Commons Ct. NE, Marietta, GA 30062, during the regular work week.

Sincerely,

Marcela Vessell

Marcela Vessell
VP, Global QA & Reg. Compliance

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

Business Name			From - To (MM/YY – MM/YY)	
MiMedx Group, Inc.			10/22 - present	
Business Address		**City**	**State**	**Zip**
1775 West Oak Commons Court, NE,		Marietta	GA	30062
Phone	**Title**		**Number of Employed Hours**	
(470) 390-2246	SR. Director Quality Engineering		6000 hours (3 years)	
Description of Duties				
Sr. Director of Quality, responsible for Quality Operations.				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			04/20 - 10/22	
Business Address		**City**	**State**	**Zip**
14420 NW 60th Ave		Miami Lakes	FL	33014
Phone	**Title**		**Number of Employed Hours**	
(305) 818-4100	Sr. Director Quality		6000 hours (3 years)	
Description of Duties				
Sr. Director of Quality, responsible for Quality Systems and Quality Operations.				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			05/18 - 04/20	
Business Address		**City**	**State**	**Zip**
Ceiba Norte Industrial Park, 50 Road 31, Km 24		Juncos	PR	00777
Phone	**Title**		**Number of Employed Hours**	
787-561-2200	Director Quality		6000 hours (3 years)	
Description of Duties				
Director of Quality, responsible for Quality Systems and Quality Operations.				

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Pedro L. Melendez Ruiz, **certify that as the MDEG Administrator for**

MIMEDX GROUP, INC.,

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

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

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

Pedro L. Melendez Ruiz
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Dec 8, 2025
Date

Board Use Only	Date Received: 12/17/25

Employee Name (Last Suffix, First MI)	Job Title	Home Dept	Location
Adams, Jasmin	Donor Recovery Specialist I	Recovery Accounts	West Oak
Adamson, Kazeem A.	Donor Recovery Assistant	Recovery Service Hrly	West Oak
Agirbas, Ece	Informatics Analyst	BI Reporting	West Oak
Ajayi, Olamide A.	Procurement Specialist	Supply Chain	West Oak
Aleman, Stephanie	Donor Recovery Specialist I	Recovery Accounts	West Oak
Allen, Ashley	Processor I	Production	West Oak
Amuti, Tanya	Sr. Accountant	Accounting	West Oak
Appling, Kendra N.	Security Supervisor	Occupancy	West Oak
Asrar, Saad	Sr Compliance Specialist	Quality Engineering	West Oak
Avery, LeTreice	Pilot Technician	R&D-Pilot Production Hrly	West Oak
Bailey, Sunaya	Manager, Strategic Procurement	Strategic Procurement	West Oak
Barnes-Howell, Shaquia	Donor Recovery Specialist I	Recovery Accounts	West Oak
Bash, Adam R.	Sales Development Specialist	Inside Sales	West Oak
Beasley, Tiffany	QA Donor Eligibility Coordinator	QARA Hourly	West Oak
Belfrom, Emmanuel A.	Processor I	Production	West Oak
Bell, Claudia	Executive Assistant	Legal	West Oak
Bender, Clint	Sr. QC Manager	Quality Control	West Oak
Bergdale, Jeffery	Accounts Receivable Manager	Finance Operations	West Oak
Berluche, Rachel	Clinical Case Manager	Reimbursement	West Oak
Bernard, Carissa E.	Account Coordinator	Customer Services Hrly	West Oak
Berry, John B.	Lead Maintenance Technician	Process Engineering Hrly	West Oak
Best, Janine	MGR, Global Regulatory Affairs	Regulatory Affairs	West Oak
Bhaskaran, Ratish	Sr. Director, Analytics	BI Reporting	West Oak
Bickham, Andrea W.	Sr. MGR, Clinical Data	BI Reporting	West Oak
Blackwood, Ashley N.	Manager, Compliance Audit Process Design	Compliance	West Oak
Blum, Andrea	Sr. Dir. Hospital & Partner Relations, Recovery	Recovery Service	West Oak
Boney, John	Sr. Manager, CRM Systems	Information Services	West Oak
Bowen, Lindsay M.	CMC Project Manager	R&D-Pilot Production	West Oak
Bresnock, Andrew M.	VP Commercial Ops	Commercial Operations	West Oak
Briggs, Jeffrey	Quality Engineer	Process Engineering	West Oak
Broach, Lindsey D.	Finance Operations AR Coordinator	Finance Operations Hrly	West Oak
Brown, Gregory	Manager, Strategic Procurement	Strategic Procurement	West Oak
Brown, Shawan L.	Sanitization Instrument Processor I	Production	West Oak
Buchanan, Kelli C.	Learning & Development Specialist	Sales-Training	West Oak
Buice, Serena T.	Quality Control Technician	Quality Control Hrly	West Oak
Bullock, Nicholas	Design Transfer Engineer	R&D-Pilot Production	West Oak
Burch, Brandon F.	Sr. Credit Analyst	Finance Operations	West Oak
Burcher, Marc	Sr. Salesforce Business Analyst	Information Services	West Oak
Burrow, Brandon E.	Sr Dir Commercial Ops	Commercial Operations	West Oak
Bussell, Nina	Account Coordinator	Customer Services Hrly	West Oak
Cammack, Lorena	Quality Engineer	Quality Engineering	West Oak
Campbell, Shauna M.	Medical Affairs Coordinator	Medical Education	West Oak
Cananzi, Kelly S.	Commissions Manager	Finance	West Oak
Carlson, Sebastian G.	Wound Associate Account Executive	Sales - EA - NEW ENGLAND	West Oak
Carmona, Jesus E.	Facilities Technician	Occupancy Hrly	West Oak
Carter, Josephine	Reimbursement Specialist	Reimbursement	West Oak
Carvajal Lopez, Claudia	Product Packager II	Production	West Oak
Castillo Jr., Eric	Systems Engineer	Information Services	West Oak
Castillo Pena, Dora	Processor II	Production	West Oak
Castillo, Aide	Packaging Supervisor	Manufacturing OH	West Oak

Celotto, Michelle C.	QA Donor Eligibility Associate	QARA Hourly	West Oak
Cespedes, Rosemary	Processor I	Production	West Oak
Charles, Angela W.	Donor Recovery Associate	Recovery Service Hrly	West Oak
Chastain, Alexis J.	QA Product Release Supervisor	QARA	West Oak
Chastain, Tracy L.	Chief Human Resources Officer	Human Resources	West Oak
Chen, Chen	Associate System Engineer	Information Services	West Oak
Clark, Terelischa K.	Donor Recovery Associate	Recovery Service Hrly	West Oak
Clements, Amanda	AR Supervisor	Finance Operations	West Oak
Clements, Lauren C.	Account Coordinator	Customer Services Hrly	West Oak
Cloud, Josie A.	Sales Development Specialist	Inside Sales	West Oak
Colt IV, Rutger B.	Quality Engineer	Process Engineering	West Oak
Cone, Shequera K.	Operations Support Coordinator	Manufacturing OH Hrly	West Oak
Cook, Margaret E.	Travel Coordinator	Finance Operations Hrly	West Oak
Copiano, Hanna	ERP Support Analyst	Information Services	West Oak
Cox, Brian D.	Director, Finance	Finance	West Oak
Crawford, Nion	Pilot Production Manager	R&D-Pilot Production	West Oak
Cruz, Shannon R.	AVP, Human Resources	Human Resources	West Oak
Davis, Brent	Donor Recovery Assistant	Recovery Service Hrly	West Oak
De Jong, Julie L.	Sr. Informatics Analyst	BI Reporting	West Oak
Deas, Todd R.	Sr. Manager, Conference & Event Planning	Marketing	West Oak
Denoziere, Guilhem	AVP, Global Regulatory Affairs	Regulatory Affairs	West Oak
Denton, Debra M.	Manager, Conference & Event Planning	Marketing	West Oak
Derai, Avi A.	Lead Maintenance Technician	Process Engineering Hrly	West Oak
Derai, Cindy C.	Processor II	Production	West Oak
Diallo, Mamadou S.	QA Donor Eligibility Specialist	QARA Hourly	West Oak
Diers, Jason	Sales Development Specialist	Inside Sales	West Oak
Dillenbeck, Anthony J.	Digital Marketing Communications Manager	Marketing	West Oak
DiNenna, Mairid C.	Sr. Accounting Manager	Accounting	West Oak
Donaldson, Jerrica S.	Processor I	Production	West Oak
Down, Nicholas	Sr. Mgr. Investor Relations & Corporate Communi	Investor Relations	West Oak
Dragicevic, Aleksandar	Manufacturing Engineer	Manufacturing OH	West Oak
Drennen, DesJia M.	Processor I	Production	West Oak
Dunlap, Jeremy N.	Business Analyst	Information Services	West Oak
Durgan, Kimberly	Director, Payroll & Commissions	Finance	West Oak
Easton, Sydney T.	Surgical Territory Manager	Sales – SG – SE	West Oak
Enwerem-Lackland Ph.D., Isioma	Research Scientist I	R&D Research	West Oak
Esters, Kenneth D.	Chief Building Engineer	Process Engineering	West Oak
Etienne, Marie-Cenande	Reimbursement Specialist	Reimbursement	West Oak
Etienne, Tia K.	Sr Complaint Coordinator	Quality Engineering	West Oak
Everett, Tony D.	Sr. Finance Operations Analyst	Finance Operations	West Oak
Faison, EdDonte D.	Sr Receiving & Inventory Associate	Distribution Svcs. Hrly	West Oak
Fettinger, Dana	Sr. Finance Operations Coordinator- AP	Finance Operations Hrly	West Oak
Figueroa, William D.	Principal Computer Validation Specialist	Quality Engineering	West Oak
Fincher, Amanda B.	Sr QA Product Release Associate	QARA Hourly	West Oak
Firment, Paul J.	Desktop Support Analyst	IT-Hrly	West Oak
Florence, Rachael	QA Inventory Specialist	QARA	West Oak
Fouse, Jonathan A.	Account Executive	Sales - SO - ATLANTA	West Oak
Frederick, Kristen	Dir. IT Business Services	Information Services	West Oak
Freeman, Natasha	Quality Control Supervisor	Quality Control	West Oak

Fruechtnicht, Nelly	Executive Assistant, CEO	Chief Executive Office	West Oak
Fulcher, Linda G.	QA Donor Eligibility Manager	QARA	West Oak
Fulcher, Ronnie F.	Metrology Program Sr. Manager	Process Engineering	West Oak
Galloway, Tajha	Sr. Payroll Specialist	Finance	West Oak
Garcia, Nelson M.	Sr. Treasury Analyst	Finance	West Oak
Gaston, Yeager	Sr. Quality Engineer	R&D-Pilot Production	West Oak
Gathers, Shamia	Regulatory Compliance Labeling PM	QARA	West Oak
Geldart, Mike	Sr. Manufacturing Engineer	Manufacturing OH	West Oak
Genevish, Scott	Director, IT Operations	Information Services	West Oak
Giron, Rigoberto J.	Processor I	Production	West Oak
Gitau, Michael	Maintenance Technician	Process Engineering Hrly	West Oak
Goins, Cristian	Sr Commercial Ops Analyst	Commercial Operations	West Oak
Gould, Patrice R.	QA Product Release Coordinator	QARA Hourly	West Oak
Grace, Kaitlyn	Sr. Quality Engineer	R&D-Pilot Production	West Oak
Gravlin, Tara	Payroll Manager	Finance	West Oak
Grimes, Marcelle C.	Account Coordinator	Customer Services Hrly	West Oak
Grundy, Patrick A.	Software Developer	Information Services	West Oak
Guerrero M.S., Jose L.	Sr. Manager, Quality Engineering	Quality Engineering	West Oak
Hall, Christie	Director, Recovery Services	Recovery Service	West Oak
Hall, Hayden	Donor Eligibility Coordinator	QARA Hourly	West Oak
Harden, Lauren	Surgical Territory Manager	Sales – SG – SE	West Oak
Harris, Latonya	Sr. Human Resources Business Partner	Human Resources	West Oak
Hartland, Angela	Sr. Tech Transfer Specialist	R&D-Pilot Production	West Oak
Hernandez, Rosa M.	Donor Recovery Associate	Recovery Service Hrly	West Oak
Herrera, Theresa W.	Executive Assistant	Sales-Administration	West Oak
Herrington, Darren	Desktop Support Analyst	IT-Hrly	West Oak
Hill, Michelle	Sr Manager Marketing Insights	Marketing	West Oak
Hilton, Leo	Manufacturing Engineer	Manufacturing OH	West Oak
Holbrook, Jennifer M.	Operations Training Manager	Manufacturing OH	West Oak
Hook, Laurel H.	Donor Recovery Specialist I	Recovery Accounts	West Oak
Hudgens, Lisa A.	Director, Enterprise Software Development	Information Services	West Oak
Huffman, Nicholas	Associate Quality Engineer	Quality Engineering	West Oak
Ibrahim, Jessica C.	Sr QA Donor Eligibility Coordinator	QARA Hourly	West Oak
Ifechidelu, Rebecca O.	Processor I	Production	West Oak
Ito, Chika	Commercial Ops Analyst	Commercial Operations	West Oak
Jackson Jr., Odes J.	Supply Chain Manager	Supply Chain	West Oak
Jackson, Ratayvius T.	Team Lead, Recovery Services	Recovery Service Hrly	West Oak
Jackson-Kincaid, Sandra	Sr QA Product Release Associate	QARA Hourly	West Oak
Jasinski, Jean-Michel	Sr. CMC Program Manager	R&D-Pilot Production	West Oak
Jefferson, Nancy S.	Sr. Contracts Specialist	Contract Administration	West Oak
Jeter, Amber	Sr. Paralegal	Legal	West Oak
Jewell, Ian M.	Sr. Quality Control Technician	Quality Control Hrly	West Oak
Jimenez, Thelma A.	Warehouse Rep III	Distribution Svcs. Hrly	West Oak
Johnson, Logan	Market Access and Pricing Manager	Contract Administration	West Oak
Jones, Iolo	Sr Commercial Ops Analyst	Commercial Operations	West Oak
Jones, Jonathan	Contracts Specialist	Contract Administration	West Oak
Jones, Judith	Processor I	Production	West Oak
Kapoor, Karishma	Market Access Specialist	Contract Administration	West Oak
Kemp, Donnta A.	Sr. Finance Operations Coordinator - AR	Finance Operations Hrly	West Oak

Kennedy, Laura	Sr Travel Coordinator	Finance Operations	West Oak
Khan, Owais	Processor I	Production	West Oak
Kittles, Nicholas	Processing Supervisor	Manufacturing OH	West Oak
Klotz, Heather	Sr Salesforce Coordinator	IT-Hrly	West Oak
Koenig, Natalie	Associate Product Development Engineer	R&D Product Development	West Oak
Komic, Daira	Sr. Manager, HCT/P	R&D-Pilot Production	West Oak
Kondaveeti, Anupama	Sr. Software Developer	Information Services	West Oak
Krawczyk Jr., Raymond	VP, Finance Operations	Finance Operations	West Oak
Kruk, Peggy	Compliance Manager	Compliance	West Oak
Lafrance, Jere N.	Customer Service Supervisor	Customer Services	West Oak
Lang, Jimmie D.	Associate Research Scientist II	R&D Research	West Oak
Larson, Matthew	Senior Director, Strategic Commercial Initiatives	National Accounts	West Oak
Lathan, Lakeina M.	Product Packager II	Production	West Oak
Lawrence, Joycelyn M.	Sr QA Product Release Associate	QARA Hourly	West Oak
Lecke, Ami J.	Manager Marketing Operations	Marketing	West Oak
Lee II, James C.	Business Intelligence Architect	BI Reporting	West Oak
Leidner, Destin B.	Processor I	Production	West Oak
Lim, Jeremy	Global Director, Regulatory Affairs	Regulatory Affairs	West Oak
Lindsay, Dakia	Sr. Quality Control Technician	Quality Control Hrly	West Oak
Lioon, Kendall	Assistant General Counsel	Legal	West Oak
Lipsey, Barbra J.	Sr. Credit Analyst	Finance Operations	West Oak
Lloyd, William H.	VP, Technology Transfer	R&D-Pilot Production	West Oak
Long, Analiza H.	QA Product Release Coordinator	QARA Hourly	West Oak
Luck, Jenny S.	Product Manager	Marketing	West Oak
Lyle, Megan D.	Sr. Finance Operations Coordinator - AR	Finance Operations Hrly	West Oak
Madan, Donya L.	Sr. Project Manager	R&D Product Development	West Oak
Maddox Jr., Frank J.	Computer System Validation Engineer	Quality Engineering	West Oak
Maddox, Eric J.	Warehouse Team Lead	Distribution Svcs. Hrly	West Oak
Madrid, Cynthia	Donor Recovery Specialist I	Recovery Accounts	West Oak
Marks, Courtney	Account Coordinator	Customer Services Hrly	West Oak
Martin, Hortense	Sr QA Product Release Associate	QARA Hourly	West Oak
Martin, Keyko A.	QA Donor Eligibility Associate	QARA Hourly	West Oak
Martin, Tawana D.	National Donor Recovery Specialist	Recovery Accounts	West Oak
Mason Jr., David H.	CMO, Head of Clinical Development	R&D-Clinical Studies	West Oak
Massee, Michelle	VP Research & Development, Wound Care & Surg	R&D Product Development	West Oak
Mbeh, Bimisimbom Y.	Sr QA Product Release Associate	QARA Hourly	West Oak
McClellan, Kelsey	Manager, Finance	Finance	West Oak
Mccroskey, Kaitlyn	Sr Mgr, MES Strategy & Deployment	Quality Engineering	West Oak
McDowell, Alexander J.	Sr Marketing Asset Management Specialist	Marketing	West Oak
McGill, David W.	Senior Director, Engineering	Process Engineering	West Oak
McManus, Christianna M.	Senior Commission Analyst	Finance	West Oak
Mcmillan, Jelena	AVP, Customer Insights	Marketing	West Oak
Mcmillian, Kendrick	Sr Distribution Associate	Distribution Svcs. Hrly	West Oak
Meyer, Tristan X.	Sr Distribution Associate	Distribution Services	West Oak
Moerschel, Katherine	Sr QA Product Release Associate	QARA Hourly	West Oak
Moncada, Lucas	Systems Engineer	Information Services	West Oak
Montano Colin, Armando	Processing Supervisor	Manufacturing OH	West Oak
Moreno M.A., Sarah E.	Director, Research	R&D Research	West Oak
Mullan, Jake	Product Development Engineer	R&D Product Development	West Oak

Musick, Brien	Facilities Manager	Occupancy	West Oak
Newsome, Jennifer	Sr. Dir, Branding and Creative Development	Marketing	West Oak
Nguyen, Elizabeth	Donor Recovery Specialist I	Recovery Accounts	West Oak
Nixon, Jamye	Quality Control Supervisor	Quality Control	West Oak
Nogueras, Clara	Warehouse Team Lead	Production	West Oak
Notarianni, Matthew M.	VP, Investor Relations	Investor Relations	West Oak
Ogundipe, Kehinde O.	Processor III	Production	West Oak
Okhigbochie, Obende S.	Finance Operations Analyst AP	Finance Operations Hrly	West Oak
Okojie, Obehi R.	Sr Distribution Associate	Distribution Svcs. Hrly	West Oak
Okoro, Uche	Sr. Quality Engineer	Quality Engineering	West Oak
Okungu, Linet R.	Credit Supervisor	Finance Operations	West Oak
Olayiwola, Hakeem A.	Processor I	Production	West Oak
Olender, Tyler	Associate Research Scientist II	R&D Research	West Oak
Oliver, Tyler	Sr Commercial Ops Analyst	Commercial Operations	West Oak
Oothoudt, Adam G.	Sr. Director, Finance	Finance	West Oak
Ortega, Jonathan	Sr. Manager, ERP Systems and Development	Information Services	West Oak
Ortiz-Ortiz, Ruth Marie	Sr. CAPA Specialist	Quality Engineering	West Oak
Owens, Eileen	Credit Manager	Finance Operations	West Oak
Ozaki, Gavin	Maintenance Technician	Process Engineering Hrly	West Oak
Palermo, Susan	Executive Assistant	R&D Admin -W&S	West Oak
Palmer, Faith S.	Learning & Development Specialist	Sales-Training	West Oak
Pannell, Leslie	QA Product Release Coordinator	QARA	West Oak
Park, Jae	Sr Human Resources Coordinator	Human Resources Hrly	West Oak
Parker, Mikala L.	Reimbursement Specialist	Reimbursement	West Oak
Parker, Tamekia	Processor I	Production	West Oak
Pathania, Ranjan	Business Intelligence Architect	BI Reporting	West Oak
Pearson, Andrew	Sr. Director, IT Applications	Information Services	West Oak
Perez-Santiago, Johanna	Sr. Document Control Coordinator	QARA Hourly	West Oak
Phanse, Ketan U.	Director, Ops Excellence	Manufacturing OH	West Oak
Phillips, Megan	Donor Recovery Specialist I	Recovery Accounts	West Oak
Phung, Yesica L.	Sr. Donor Recovery Specialist	Recovery Accounts	West Oak
Piede, Tyler D.	Controller	Accounting	West Oak
Pratt, K'Andria A.	Supervisor, Recovery Services	Recovery Service	West Oak
Pressley, Elliott	Pilot Technician	R&D-Pilot Production Hrly	West Oak
Pulipati, Naresh	MES Manager	Manufacturing Admin	West Oak
Ramirez Contreras, Javier	Sr. Quality Engineer	Quality Engineering	West Oak
Ray, Courtney C.	Account Coordinator	Customer Services Hrly	West Oak
Reames III, Carter	Sr Salesforce Coordinator	IT-Hrly	West Oak
Reed, Nikita	QA Donor Eligibility Supervisor	QARA	West Oak
Reid, Abigail	Credit Analyst	Finance Operations Hrly	West Oak
Rembert, Bernice	Manager, Finance Operations	Finance Operations	West Oak
Rembert, Nelson M.	Donor Review Coordinator	Recovery Service Hrly	West Oak
Renrick Ph.D., Ariana N.	Research Scientist I	R&D Research	West Oak
Riley, Brian	VP, Finance	Finance	West Oak
Roark M.S., Paul D.	Commercial Ops Analyst	Commercial Operations	West Oak
Roberts, Brian	Desktop Support Analyst	IT-Hrly	West Oak
Roberts, Chelsea	Donor Review Coordinator	Recovery Service Hrly	West Oak
Roberts, Keith R.	Vice President, Project Management QOR	Manufacturing Admin	West Oak
Robinson, Shana A.	Senior Corporate Recruiter	Human Resources	West Oak

Robinson, Teyiana M.	Purchasing Analytics Specialist	Supply Chain	West Oak
Rodriguez, Felix	Director Processing	Manufacturing OH	West Oak
Rodriguez, Lizmarie	QA Product Release Coordinator	QARA Hourly	West Oak
Rodriguez, Maria F.	Processor I	Production	West Oak
Rogers, Erika	Donor Recovery Specialist I	Recovery Accounts	West Oak
Rogers, Yasmine	Inventory Analyst II	Finance	West Oak
Rollins, Lucinda R.	Recovery Operations Specialist	Recovery Service Hrly	West Oak
Rosas Moran, Naretsi G.	Product Development Manager	R&D Product Development	West Oak
Ruf, Jennifer	Sr Commercial Ops Analyst	Commercial Operations	West Oak
Ruiz, Renzo P.	Sr Finance Ops Associate AP	Finance Operations Hrly	West Oak
Rumph, Courtney L.	Warehouse Team Lead	Distribution Svcs. Hrly	West Oak
Salazar, Thalia I.	Donor Recovery Specialist I	Recovery Accounts	West Oak
Saunders, Erik	Sr. CAPA Specialist	Quality Engineering	West Oak
Savage, Rachel	VP, Marketing	Marketing	West Oak
Shirley III, Robert A.	Account Coordinator	Customer Services Hrly	West Oak
Shirley, Heather	Sr QA Donor Eligibility Coordinator	QARA Hourly	West Oak
Sims, Antoinette L.	Operations Support Coordinator	Manufacturing OH Hrly	West Oak
Sims, Jordan	Financial Analyst	Finance	West Oak
Sinha, Ankur	Sr. ETL Architect	BI Reporting	West Oak
Skinner Jr., Frederick J.	Metrology Technician	Process Engineering	West Oak
Skinner, Kirstie N.	Wound Account Executive	Sales - SO - ATLANTA	West Oak
Slayton, Michael	Informatics Analyst	BI Reporting	West Oak
Smallwood, Donald E.	Senior Director, Talent Acquisition	Human Resources	West Oak
Smart, Ernestine	Sanitization Instrument Processor I	Production	West Oak
Smith, Adam	Wound Account Executive	Sales - SO - ATLANTA	West Oak
Smith, Antonio	Sr. Software Developer	Information Services	West Oak
Smith, Dorcas	Sr. Manager, Quality Systems	QARA	West Oak
Smith, Richard W.	Supervisor Warehouse	Distribution Svcs. Hrly	West Oak
Smith, Shakesia	Pilot Technician	R&D-Pilot Production Hrly	West Oak
Snyder, Mary E.	Staff Accountant	Accounting	West Oak
Spencer, Randall	VP, Clinical Innovations	Medical Education	West Oak
Spruiell, Jeff	Distribution Manager	Distribution Services	West Oak
Steck, Haley	Donor Recovery Specialist I	Recovery Accounts	West Oak
Stefanie, Anthony	QA Donor Eligibility Associate	QARA Hourly	West Oak
Stevens, Sade	QA Product Release Supervisor	QARA	West Oak
Stewart, Sharea	Processor I	Production	West Oak
Stiles, Garrett	Field Reimbursement Mgr	Reimbursement	West Oak
Stinson, Lakaiya D.	Sr QA Product Release Associate	QARA Hourly	West Oak
Stock, Sydney L.	Associate Product Development Engineer II	R&D Product Development	West Oak
Strauss, Ronald F.	VP, Compliance	Compliance	West Oak
Strickland, Terriyaka	QA Donor Eligibility Coordinator	QARA Hourly	West Oak
Swathy Ganga, Fnu	Accountant	Accounting	West Oak
Sweetman, Ryan	Process Engineer	Process Engineering	West Oak
Swicegood, Caroline	Financial Analyst	Finance	West Oak
Tabak, Nicholas E.	Quality Control Technician	Quality Control Hrly	West Oak
Tarnowski, Lisa J.	Executive Assistant	Marketing	West Oak
Tavares, Ana	Sr. QA Donor Eligibility Specialist	QARA	West Oak
Taylor, Christine D.	Distribution Coordinator	Distribution Svcs. Hrly	West Oak
Taylor, Joann J.	Contracts Specialist	Contract Administration	West Oak

Taylor, Kirstyn E.	Quality Control Specialist	Quality Control	West Oak
Tedjohartoko, Brittany	Processor I	Production	West Oak
Thompson, Ryan	Credit Analyst	Finance Operations Hrly	West Oak
Threadgill, Taelor L.	Contracts Specialist	Contract Administration	West Oak
Torres, Anahi	Desktop Support Analyst	IT-Hrly	West Oak
Trainer, Mark	Assistant General Counsel	Legal	West Oak
Turner, Caroline	Executive Assistant	QARA	West Oak
Turner, Scott M.	SVP, Strategic Procurement	Strategic Procurement	West Oak
Turner, Taylor	Manager, Data Governance and Master Data	Manufacturing Admin	West Oak
Uchenye, Patience C.	Processing Supervisor	Manufacturing OH	West Oak
Ulloa Sanchez, Maria F.	Donor Recovery Specialist I	Recovery Accounts	West Oak
Uroda, Melanie	Quality Engineer	R&D-Pilot Production	West Oak
Vessell, Marcela R.	VP, Global QA & Reg. Compliance	QARA	West Oak
Wagner, Stephanie M.	Account Coordinator	Customer Services Hrly	West Oak
Waid, Matthew B.	Sr Commercial Ops Manager	Commercial Operations	West Oak
Waid, Sarah E.	Manager, Business Intelligence	BI Reporting	West Oak
Ward, Julie	Quality Control Technical Review Coordinator	Quality Control Hrly	West Oak
Washington, Harold F.	Metrology Tech II	Process Engineering Hrly	West Oak
Westmoreland, Kitta	Operations Support Coordinator	Manufacturing OH Hrly	West Oak
White, Alexis M.	Information Security Analyst	Information Services	West Oak
Whorton, Da'vicka S.	Product Packager II	Production	West Oak
Whyte, Jason M.	Manager, Quality Engineering	Process Engineering	West Oak
Widemond, Tomas	Sr. Manager Environment, Health, Safety & Facilit	Occupancy	West Oak
Wilcher, Brittany	Donor Recovery Specialist I	Recovery Accounts	West Oak
Williams, Jewell E.	Manufacturing Engineer	Manufacturing OH	West Oak
Williams, Kourtney	Corporate Recruiter	Human Resources	West Oak
Williamson, Julie A.	Sr Salesforce Administrator	Information Services	West Oak
Woodard, William	Sr. Credit Analyst	Finance Operations	West Oak
Woods, Tugwan D.	Sr. HRIS Manager	Human Resources	West Oak
Worthy, Renee	Processor I	Production	West Oak
Wray, Britney-Ann	Donor Recovery Specialist I	Recovery Accounts	West Oak
Wright, Laura	Market Access Specialist	Contract Administration	West Oak
Wyatt, Deon	Sr. Manager, Distribution Services & Packaging	Distribution Services	West Oak
Yosick, Mark J.	Sr Director Marketing	Marketing	West Oak
Zeigler, Tea	Manager Benefits	Human Resources	West Oak

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-35887

MIMEDX GROUP, INC.

(Exact name of registrant as specified in its charter)

Florida	**26-2792552**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1775 West Oak Commons Court, NE, Marietta, GA

(Address of principal executive offices)

30062

(Zip Code)

(770) 651-9100

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None.

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	MDXG	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§223.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered accounting firm that prepared or its audit report ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the registrant's voting common equity held by non-affiliates of the registrant as of June 28, 2024 (the last business day of the registrant's most recently completed second quarter) was approximately $803.7 million based upon the last sale price ($6.93) of the shares as reported on The Nasdaq Stock Market LLC on such date.

There were 147,366,056 shares of the registrant's common stock, par value $0.001 per share, outstanding as of February 25, 2025.

Documents Incorporated By Reference

Portions of the proxy statement relating to the 2025 Annual Meeting of Shareholders, to be filed within 120 days after the end of the fiscal year to which this report relates, are incorporated by reference in Part III of this Report.

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PART I

Explanatory Note and Important Cautionary Statement Regarding Forward-Looking Statements

As used herein, the terms "MIMEDX," "the Company," "we," "our" and "us" refer to MiMedx Group, Inc., a Florida corporation, and its consolidated subsidiaries as a combined entity, except where it is clear that the terms mean only MiMedx Group, Inc.

The following discussion should be read in conjunction with the financial statements and related notes contained elsewhere in this Annual Report. Certain statements made in this Annual Report are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "***Securities Act***"), and Section 21E of the Securities Exchange Act of 1934, as amended. All statements relating to events or results that may occur in the future are forward-looking statements, including, without limitation, statements regarding the following:

- our strategic focus and our current business priorities, and our ability to implement these priorities;
- the advantages of our products, development of new products and expansion of our product offering;
- our expectations regarding potential markets for our products, including a growing number of surgical specialties, the size of potential markets and any growth in such markets;
- our expectations regarding expansion in current markets for our products;
- our expectations regarding ongoing regulatory obligations and oversight and the changing nature thereof impacting our products, research and clinical programs, and business;
- our expectations regarding Medicare reimbursement reform involving certain of our products and our ability to secure Medicare reimbursement for additional products in the future;
- our expectations regarding our ability to procure sufficient supplies of human tissue to manufacture and process our existing and future products;
- our expectations regarding costs relating to compliance with regulatory requirements;
- our expectations regarding our systems and their ability to ensure the Company's compliance with regulations;
- our intention to implement and maintain rigorous quality standards through the Company's supply chain and to advance the scientific body of evidence substantiating the clinical efficacy of our products;
- our expectations regarding the sufficiency of our insurance;
- our expectations regarding government and other third-party coverage and reimbursement for our products;
- our expectation that we will not pay cash dividends and will use available funds in the development, operation, and expansion of our business, to repay debt, and, to the extent authorized by our Board, repurchase Common Stock;
- our belief that our properties are suitable and adequate to meet the needs of our business;
- our expectations regarding the outcome of pending litigation and investigations;
- our belief in the sufficiency of our intellectual property rights in our technology;
- our expectations regarding future income tax liability;
- our belief that we will be able to meet our operational liquidity needs;
- demographic and market trends; and
- our ability to compete effectively.

Forward-looking statements generally can be identified by words such as "expect," "will," "change," "intend," "seek," "target," "future," "plan," "continue," "potential," "possible," "could," "estimate," "may," "anticipate," "to be" and similar expressions. These statements are based on numerous assumptions and involve known and unknown risks, uncertainties and other factors that could significantly affect our operations and may cause our actual actions, results, financial condition, performance or achievements to differ materially from any future actions, results, financial condition, performance or achievements expressed

or implied by any such forward-looking statements. Factors that may cause such a difference include, without limitation, those discussed in Item 1A, *Risk Factors* in this Annual Report.

Unless required by law, the Company does not intend, and undertakes no obligation, to update or publicly release any revision to any forward-looking statements, whether as a result of the receipt of new information, the occurrence of subsequent events, a change in circumstances or otherwise. Each forward-looking statement contained in this Annual Report is specifically qualified in its entirety by the aforementioned factors. Readers are advised to carefully read this Annual Report in conjunction with the important disclaimers set forth above prior to reaching any conclusions or making any investment decisions and not to place undue reliance on forward-looking statements, which apply only as of the date of the filing of this Annual Report with the SEC.

Summary of Risk Factors

Risks Related to Our Business and Industry

- If we do not successfully execute our priorities, our business, operating results and financial condition could be adversely affected.
- We are in a highly competitive and evolving field and face competition from well-established tissue processors and medical device manufacturers, as well as new market entrants.
- Rapid technological change could cause our products to become obsolete.
- Many of our products depend on the availability of tissue from human donors, and any disruption in supply could adversely affect our business.
- We depend on our senior leadership team and key employees and may not be able to retain or replace these employees or recruit additional qualified personnel.
- Our revenues depend on adequate reimbursement from public and private insurers and health systems and changes to the way in which our products are reimbursed in various sites of service could adversely impact our financial results.
- Our revenue, results of operations and cash flows may suffer upon the loss of a Group Purchasing Organization or Integrated Delivery Network.
- We contract with and are dependent on independent sales agents and distributors.
- Disruption of our processing facilities could adversely affect our business, financial condition and results of operations.
- To be commercially successful, we must educate physicians, where appropriate, how and when our products are proper alternatives to existing treatments and that our products should be used in their procedures.
- If we cannot successfully address quality issues that may arise with our products, our brand reputation could suffer, and our business, financial condition, and results of operations could be adversely impacted.
- The formation of physician-owned distributorships could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.
- We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.
- The products we offer are derived from human and animal tissue and therefore have the potential for disease transmission.
- We may implement a product recall or voluntary market withdrawal.
- A cyberattack or significant disruptions of information technology systems could adversely affect our business.
- We may expand or contract our business through acquisitions, divestitures, licenses, investments, and other commercial arrangements.
- A portion of our revenues and accounts receivable come from government accounts.
- New lines of business or new products and services may subject us to additional risks.
- Our international expansion and operations outside the U.S. expose us to risks.

Risks Related to Regulatory Approval of Our Products and Other Government Regulations

- The FDA has in the past determined, and may in the future determine, that certain of our products that are, or are derived from, human cells or tissues, do not qualify for regulation solely under Section 361 of the Public Health Service Act ("Section 361"), and may require that we revise our labeling and marketing claims for these products or that we suspend sales of such products until FDA pre-market clearance or approval is obtained, which could adversely affect our business, results of operations, and financial condition.
- Obtaining and maintaining the necessary regulatory approvals, including conducting clinical trials, for certain of our products will be expensive and time consuming and may impede our ability to fully exploit our technologies.
- Our business is subject to extensive regulation by the FDA and other authorities, which is costly.
- We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off-label, uses.
- We and our sales representatives must comply with various federal and state anti-kickback, self-referral, false claims and similar laws.
- Our results of operations may be adversely affected by current and potential future healthcare reforms.
- We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.
- Federal, state, and international laws that protect the privacy and security of personal information may increase our costs and limit our ability to collect and use that information and subject us to liability.

Risks Related to Our Intellectual Property

- Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and may be inadequate.
- We may become subject to claims of infringement of the intellectual property rights of others.
- We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets, proprietary or confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Risks Related to Our Consolidated Financial Statements, Internal Controls and Related Matters

- If we fail to maintain adequate internal control over financial reporting in the future, this could adversely affect our business, financial condition and operating results.

Risks Related to the Ownership of Our Common Stock

- The restrictive covenants in the Citizens Credit Agreement, and the Company's obligation to make payments under the Citizens Credit Agreement, limit our operating and financial flexibility.
- EW Healthcare Partners and its interests may conflict with those of our other shareholders.
- The price of our Common Stock has been, and will likely continue to be, volatile.
- Securities analysts may elect not to report on our common stock or may issue negative reports that adversely affect the stock price.
- Fluctuations in revenue or results of operations could cause additional volatility in our stock price.
- We do not intend to pay cash dividends on our Common Stock.
- Certain provisions of Florida law and anti-takeover provisions in our organizational documents may discourage or prevent a change of control.

Estimates and Projections

This discussion includes certain estimates, projections and other statistical data. These estimates and projections reflect management's best estimates based upon currently available information and certain assumptions we believe to be reasonable. These estimates are inherently uncertain, subject to risks and uncertainties, many of which are not within our control, have not been reviewed by our independent auditors and may be revised as a result of management's further review. In addition, these

estimates and projections are not a comprehensive statement of our financial results, and our actual results may differ materially from these estimates and projections due to developments that may arise between now and the time the results are final. There can be no assurance that the estimates will be realized, and our results may vary significantly from the estimates, including as a result of unexpected issues in our business and operations. Accordingly, you should not place undue reliance on such information. Projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. See Item 1A, *Risk Factors* for further information.

Item 1. Business

Overview

MIMEDX is a pioneer and leader in placental biologics focused on helping humans heal. With more than a decade of helping clinicians manage chronic and other hard-to-heal wounds, MIMEDX is dedicated to providing a leading portfolio of products for applications in the wound care, burn, and surgical sectors of healthcare. The Company's vision is to be the leading global provider of healing solutions through relentless innovation to restore quality of life.

With deep expertise, leading peer-reviewed data and an expansive library of additional scientific and real-world evidence in the field of placental biologics, MIMEDX develops and distributes placental tissue allografts that are manufactured using patent-protected, proprietary processes for multiple sectors of healthcare. Additionally, we began offering animal-derived products, or xenografts, in 2024 and have plans to further expand our product offering to serve our large and growing customer base.

Today, our product offering is comprised of solutions designed to help clinicians treat patients suffering from chronic and other hard-to-heal wounds, primarily in the wound care, burn, and surgical sectors of healthcare. These wounds can be slow to respond or unresponsive to conventional treatments and may benefit from advanced treatments, such as through the use of our products, in order to support the healing process.

Our placental allografts are human tissues that are derived from one person (the donor) and used to process products that treat multiple people (the recipients). The manufacturing of our human derived product offering begins with donated birth tissue, namely the human placental membrane, umbilical cord and the placental disc, which we source through a large donor network developed over multiple years with leading hospitals and clinician groups. In partnership with these facilities, we are able to obtain donated birth tissue from consenting mothers, which then are shipped to our manufacturing facilities in Marietta, Georgia, and undergo a series of testing followed by our proprietary tissue manufacturing workflow, which we refer to as the PURION® process. MIMEDX has supplied over three million allografts, through all shipments, filling direct orders and consignment orders, through December 31, 2024.

In 2024, we obtained the exclusive rights for and launched our first xenograft product and first U.S. Food & Drug Administration ("***FDA***") 510(k)-cleared product, HELIOGEN™ Fibrillar Collagen Matrix, a particulate product aimed at addressing complex wounds primarily in the surgical setting. HELIOGEN is manufactured by Regenity Biosciences, a developer and manufacturer of bioresorbable technologies.

We employ Current Good Tissue Practices ("***CGTP***") and terminal sterilization to produce our allografts. All of our products sold in the United States are regulated by the FDA, and to the extent we sell our products outside the United States, by other regulatory agencies in such international markets.

We devote significant research and development resources and expertise to the therapeutic potential of human derived, animal derived and synthetic tissues in an effort to grow our product offering, develop innovative products that address a wide range of chronic and acute health conditions affecting large patient populations, and generate best-in-class clinical evidence and data to support the use of our products.

Market Overview

Domestic sales currently account for the vast majority of our revenue today. In the United States, our primary areas of clinical use include applications in surgical settings as well as for the treatment of wounds and burns. Additionally we continue to pursue international expansion, primarily targeting Japan, as discussed below.

Wound

The unmet need for healing solutions is large and growing, with an estimated 1-2% of the population in developed countries and worldwide experiencing a chronic wound sometime in their lives[1]. In the U.S., the most recently available data indicates that chronic wounds affect 10.5 million Medicare beneficiaries and nearly 2.5% of the total population in the U.S.[2] The treatment of chronic wounds with advanced treatments is often referred to as Advanced Wound Care ("***AWC***"). Chronic wounds are defined and characterized as those that do not progress through the normal process of healing and remain open for an extended period of time, which, depending on the wound, can be from several weeks to a few months. There are numerous underlying causes of these wounds, with this patient population typically sharing some combination of comorbidities, including age, obesity, smoking history, diabetes and underlying heart and vascular diseases. Due to the rising incidence of each of these factors, we expect the AWC market will continue to grow worldwide.

Patients present with chronic wounds in a variety of care settings and these wounds vary in severity and complexity to treat. Our products can be found in many of these sites of service, including the private physician office (e.g., podiatry clinics), wound care centers, hospital inpatient and outpatient settings, nursing homes and federal facilities, such as those operated by the Department of Veterans Affairs ("***VA***"). The most common types of chronic and hard-to-heal wounds appear in the lower extremities, presenting as diabetic foot ulcers ("***DFUs***"), venous leg ulcers ("***VLUs***"), and pressure ulcers, among others. Taken together, nearly 60% of the chronic wounds in the U.S. are categorized as chronic leg ulcers (which include DFUs and VLUs), with 47% of these wounds treated with Advanced Wound Care dressings such as skin substitutes[3]. These wounds require intervention and active management by clinicians and are treated in a variety of sites-of-service, with numerous products aimed at achieving healing for the patient. The costs associated with treatment and management of patients with acute and chronic wounds is also high, with some estimates of the Medicare spend associated with such wounds approaching $100 billion annually.

The large and increasing number of patients requiring advanced treatment represents a significant cost burden on the healthcare system. The overall cost of treating chronic wounds is rising sharply, and the annual estimated cost in the United States has recently been estimated to exceed $28 billion[4].

Complications from non-healing chronic wounds can ultimately result in significant, life-altering adverse outcomes, such as limb amputation[5]. Ineffective wound management is linked to numerous poor outcomes for patients, up to and including the potential for amputation of the extremity where the wound is present. Amputation is a catastrophic event for patients, with significant impacts to their quality of life, the lives of their caretakers and the expense burden on the healthcare system. Today, up to one-fifth of diabetic patients who develop a DFU will require some form of amputation. Further, patients who undergo a major lower extremity amputation have an increased five-year mortality rate that is comparable to, and in some cases higher than, patients with many forms of cancer[6].

Advances in managing chronic and hard-to-heal wounds with solutions such as our EPIFIX® product have been shown to help contribute to improved outcomes for these patients. It is estimated that up to 85% of amputations are avoidable with a holistic, multispecialty team approach that incorporates innovative treatments, such as MIMEDX's products, and adherence to treatment parameters. MIMEDX is a leader in the cellular tissue products/skin substitute segment of the AWC category and the amniotic tissue allograft sub-category.

The AWC market is comprised of many product types, such as medical devices, advanced dressings, xenografts, synthetically derived grafts, biological products, and Human Cells, Tissues, and Cellular and Tissue - Based Products (***"HCT/Ps"***), which are used as skin substitutes to treat severe and chronic wounds. Not included in AWC are traditional wound care dressings, such as bandages, gauzes and ointments, which typically are used in the treatment of non-severe or non-chronic wounds.

The prevalence of both acute and chronic wounds has grown not only in the U.S., but also globally. While historically we have focused primarily on the U.S. market, we are in the process of expanding our footprint internationally, most notably in Japan where EPIFIX is the first and currently the only amniotic tissue product approved in the country for wound treatment across a broad range of conditions. We believe our first-mover advantage, favorable reimbursement rate, and strong distribution partner set us up for long-term success in this large and growing market.

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[1] Chronic Wounds Primer, https://pmc.ncbi.nlm.nih.gov/articles/PMC10352385/

[2] Human Wound and Its Burden: Updated 2022 Compendium of Estimates, https://pmc.ncbi.nlm.nih.gov/articles/PMC10615092/

[3] GlobalData. 2022 Wound Care Management- Tissue Engineered Skin Subs U.S. Updated May 2022

[4] Chronic Wounds: Economic Impact & Costs to Medicare, https://www.woundcarestakeholders.org/news/studies-and-publications/chronic-wounds-economic-impact-costs-to-medicare

[5] Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7092527/#CR1

[6] Epidemiology and Risk of Amputation in Patients With Diabetes Mellitus and Peripheral Artery Disease, https://www.ahajournals.org/doi/10.1161/ATVBAHA.120.314595

Traditional dressings such as bandages, gauzes and ointments, along with treatment of active infection and debridement, currently represent the "standard of care" for treating chronic wounds such as DFUs and VLUs. If, after four weeks of standard of care therapy, the wound has not responded appropriately or improved, clinical research has shown that advanced therapy such as a skin substitute can be beneficial as part of the patient's treatment plan. Our EPIFIX, EPICORD® and EPIEFFECT® products can be stored at room temperature for up to five years, in contrast to certain other skin substitutes currently on the market that have performance, storage or handling limitations. In addition, we market multiple sizes of EPIFIX, EPICORD and EPIEFFECT sheets for use as protective barriers, which enables a healthcare provider to select an appropriate size graft based on the size of the wound to reduce product waste. Our EPICORD, EPICORD Expandable and EPIEFFECT product lines also offer an alternative treatment option to address larger, deeper wounds in a cost-effective way at a point earlier in the treatment algorithm.

With broad commercial payor coverage, Medicare coverage under the Local Coverage Determinations ("***LCDs***") scheduled for implementation in April 2025, the largest body of Level 1 clinical evidence among placental allograft products and a dedicated sales team calling on each of the major sites-of-service, we expect to continue to expand our presence in the AWC market, driving future growth of our business[7].

Surgical

In addition to our presence in the AWC settings, our products are also used in a variety of surgical settings, and our strategic goals include building a body of evidence and real-world use data for our products in a wide range of procedures. The applications in Surgical range from those involving the closure of an acute wound (which we refer to as "***Surgical Recovery***"), to those where our allografts are used inside the body to protect or reinforce tissues and/or regions of interest.

Acute wounds are defined as those that are recent, are acquired from an incision or trauma and have yet to progress through the sequential stages of wound healing. Acute wounds can be caused accidentally or they can arise in the normal course of a wide-range of surgical procedures. When acute wounds present in patients with similar comorbidities to those of chronic wound patients, the risk of a slow or ineffective healing wound increases, and the risk of a surgical site infection or other similar complication increases for the patient.

In other surgical settings, the use of our products in a wide range of procedures presents a growing number of meaningful opportunities for our business. For example, the use of our tissues in anastomotic procedures has shown a statistically significant reduction in complications arising from leaks. In other procedures, the need to protect sensitive nerves, tissues or other areas may occur. We are working with surgeons in a range of disciplines to build the body of clinical, scientific and health outcomes evidence to support the use of our products broadly. We believe our product offering is ideally suited for applications in a growing number of surgical specialties that we are targeting and expect the utilization of our products to continue to grow over time in this market.

Our strategy is to continue to deliver advanced products that serve patient needs within the Advanced Wound Care and Surgical markets and increase access to our products through clinical data generation and physician education.

Our Strategic Priorities

We manage our business by focusing on the following strategic priorities, which we believe are paramount to the success of MIMEDX over the short- and long-term.

Our first priority is to innovate and diversify our product portfolio to maximize growth. Achievement of this priority is measured by our ability to maximize our commercial opportunities in the markets we serve with existing and future products, continue to introduce new products from our organic pipeline, such as the late-2023 launch of EPIEFFECT as well as the 2024 launch of HELIOGEN and accelerate market expansion internationally with a particular focus on continuing to grow our presence in Japan.

Our second priority is to develop and deploy programs to expand our surgical footprint. We believe our ability to further penetrate the surgical setting is significant and will be enabled by our ability to leverage our existing evidence for surgical applications, invest in additional research and data in new indications and to drive market adoption of new surgical products, like our recently launched HELIOGEN offering.

Our third priority is to enhance our customer intimacy, which is a company-wide effort intended to implement programs and introduce offerings in support of lowering customer turnover. To that end, in March 2024 we launched MIMEDX Connect, an

[7] Zelen CM, et al. Int Wound J. 2013;10(5):502-507. 2. Zelen CM. J Wound Care. 2013;22(7):347-351. 3. Zelen CM, et al. Wound Medicine. 2014;4:1-4. 4. Zelen CM, et al. Int Wound J. 2014;11(2):122-128. 5. Zelen CM, et al. Int Wound J. 2015;12(6):724-732. 6. Zelen CM, et al. Int Wound J. 2016;13(2):272-282. 7. Tettelbach W,et al. Int Wound J. 2019;16(1):122-130. 8. Serena TE, et al. Wound Repair Regen. 2014;22(6):688-693. 9. Bianchi C, et al. Int Wound J. 2018;15(1):114-122. 10. Bianchi C, et al. Int Wound J. 2019;16(3):761-767.

online product ordering and account management portal available to our customers designed to streamline ordering, payment processing and reimbursement submissions,

We believe execution of these strategic priorities can and will differentiate the value of our portfolio, address multiple areas of significant unmet clinical need, and support our continued growth in both new and existing segments of the market. We have focused our priorities on initiatives across our organization that position us to realize our commercial ambitions over the long-term while also generating a profitable, cash flow positive business capable of self-funding our future growth objectives.

Our Product Portfolio & Pipeline

Our product offering is comprised of tissue allografts derived from human placental membrane, umbilical cord and the placental disc. These products were developed and are manufactured using our proprietary processes. We sell our placenta-based allograft products under our own brands. We maintain strict controls on quality at each step of the manufacturing process beginning at the time of procurement. Our Quality Management System is focused on compliance with the American Association of Tissue Banks' ("***AATB***") standards, the FDA's CGTP regulations, and applicable foreign regulations.

Our Wound products, such as EPIFIX are marketed for external use, such as in Advanced Wound Care applications, while products such as AMNIOEFFECT are positioned for use in Surgical applications, including lower extremity repair, plastic surgery, vascular surgery and multiple orthopedic repairs and reconstruction, and our AXIOFILL product is positioned for use in the replacement or supplementation of damaged or inadequate integumental tissue. Our product portfolio also includes products for the burn market and others.

In 2024, we launched HELIOGEN, our first xenograft (animal-derived) and our first 510(k) cleared product in our portfolio. HELIOGEN is an advanced bovine collagen matrix containing type I and type III collagen that is intended for the management of moderately to heavily exudating wounds and to control minor bleeding. The product may be used for the management of exudating wounds such as pressure ulcers, venous stasis ulcers, diabetic ulcers, acute wounds, such as trauma and surgical wounds, and partial-thickness burns.

We continue to research new opportunities for additional human and animal derived products in a variety of configurations and sizes, and we have additional offerings in various stages of conceptualization and development.

Placenta Donation Program

In order to obtain the source material for our human birth tissue-based product portfolio, we partner with physicians and hospitals to recover donations of these materials at hospitals around the United States. Through our donor program, a mother who delivers a healthy baby via Caesarean section can donate her placenta and umbilical cord tissue in lieu of having it discarded as medical waste. After consent for donation is obtained, a blood sample from each donor is tested for communicable diseases, and the donor is screened for risk factors to determine eligibility in compliance with federal regulations and AATB standards. We operate a licensed tissue bank that is registered as a tissue establishment with the FDA, and we are an accredited member of the AATB. All donor records and test results are reviewed by our Medical Director and staff prior to the release of the tissue for distribution.

We have developed a large, geographically diverse, network of hospitals across the United States that participate in our placenta donation program, and we employ a dedicated staff that work with these hospitals. We also utilize third-party providers of placenta donations on an as- needed basis to mitigate business risk. We believe that we will be able to obtain an adequate supply of tissue to meet anticipated demand for the foreseeable future.

Processing (Manufacturing)

The Company has developed and patented a unique and proprietary technique (PURION) for processing allografts from the donated placental tissue. This technique specifically focuses on preserving the tissue's natural growth factor content and regulatory proteins and maintaining the structure and collagen matrix of the tissue. Our patented and proprietary processing method employs aseptic processing techniques in addition to terminal sterilization for increased product safety. Despite starting with similar placental tissues, all placental tissue products and processing methods are not the same – we believe that our proprietary process preserves more of the natural beneficial characteristics of the tissue than the processes used by many of our competitors.

The PURION process produces an allograft that retains the tissue's inherent biological properties and regulatory proteins (including cytokines, chemokines, and growth factors) found in the placental tissue and produces an allograft that is safe and easy for healthcare providers to use. Our allografts can be stored at room temperature and have a five-year shelf life. Each sheet allograft incorporates specialized visual markings that assist the health care practitioner with allograft placement and orientation.

To ensure the safety of human tissue products, the FDA enforces CGTP manufacturing regulations. We believe that MIMEDX has developed robust systems to comply with, and is in compliance with, these regulations. As an important part of the Company's product safety compliance, MIMEDX products are terminally sterilized to an internationally recognized industry standard in addition to having been processed *via* the PURION process.

Our facilities are subject to periodic announced and unannounced inspections by regulatory authorities and may undergo compliance inspections conducted by the FDA and corresponding state and foreign agencies. We are registered with the FDA as a tissue establishment and are subject to the FDA's CGTP quality program regulations, state regulations, and regulations promulgated by various regulatory authorities outside the United States.

The FDA most recently inspected our Marietta, Georgia, and Kennesaw, Georgia, processing facilities in 2023. At the conclusion of the inspections, the agency confirmed that the observations made in connection with its prior inspection in 2019 had all been satisfactorily closed out and/or resolved and there were no observations relating to noncompliance with 21 CFR 1271.

During the inspections, the FDA communicated that our product, AXIOFILL, appeared to be regulated under Section 351 of the Public Health Service Act (the "***PHS Act***"). Based on this position, the FDA inspected the facilities related to AXIOFILL production using regulations 21 CFR 210 and 211, relating to finished pharmaceutical products in addition to 21 CFR 1271, relating to HCT/Ps (as defined below). The FDA issued a Form 483, which is a list of inspectional observations, at the conclusion of each inspection. Specifically, the FDA issued a Form 483 consisting of one (1) observation at our Marietta, Georgia, processing facility, and a Form 483 consisting of six (6) observations at our Kennesaw, Georgia, processing facility. All observations were related to our AXIOFILL product and 21 CFR 211.

Subsequent to the inspections, MIMEDX engaged with the FDA regarding the observations and the appropriate classification of AXIOFILL, including a pre-Request for Designation ("***RFD***") and a formal RFD process, which define the regulatory identity or classification of a product as a drug, device, biological product or combination product. While the Company was engaged with FDA through the formal RFD process regarding AXIOFILL, MIMEDX received a Warning Letter on December 21, 2023, relating to the inspections and classification of AXIOFILL.

In March 2024, the FDA issued a determination letter in connection with the RFD process for AXIOFILL, reaffirming its position that the product does not meet the regulatory classification requirements of a Human Cell, Tissue or Cellular or Tissue-based Product ("***HCT/P***") under Section 361 of the Public Health Service Act ("***PHSA***"). In response to the RFD determination letter, MIMEDX subsequently filed suit in the U.S. District Court for the Northern District of Georgia and intends to exhaust all legal options available, given the arbitrary and capricious manner in which FDA is regulating like-kind products. These proceedings are ongoing. Notably, while these proceedings are taking place, the Company is permitted to continue marketing AXIOFILL.

Intellectual Property

Our intellectual property includes owned and licensed patents, owned and licensed patent applications and patents pending, proprietary manufacturing processes and trade secrets, and trademarks associated with our technology. We believe that our patents, proprietary manufacturing processes, trade secrets, trademarks, and technology licensing rights provide us with important competitive advantages.

Patents and Patent Applications

Due to the substantial expertise and investment of time, effort and financial resources required to bring new regenerative biomaterial products and implants to the market, the importance of obtaining and maintaining patent protection for significant new technologies, products and processes cannot be underestimated. As of the date of the filing of this Annual Report, in addition to international patents and patent applications, we own 81 U.S. patents related to our amniotic tissue technology and products, and 12 additional patent applications covering aspects of this technology are pending at the United States Patent and Trademark Office. The vast majority of our domestic patents covering our core amniotic tissue technology and products will not begin to expire until August 2027. Globally, the Company has over 200 issued and pending patents, and from time to time seeks to enforce its intellectual property rights.

Marketing and Sales

Our direct sales team includes field sales representatives and field sales management, who call on hospitals, wound care clinics, physician offices, and federal health care facilities such as the VA and Department of Defense ("***DoD***") hospitals. Our direct sales force primarily focuses on the Wound and Surgical categories through multiple sites of service. We also maintain a network of independent sales agents that focus on Surgical applications leveraging the complementary products in their

portfolios, and provide access to certain customers, as well as sales coverage for areas where we do not have a full-time sales representative.

We also sell our products through distributors. Distributors purchase products from us at wholesale prices and resell products to providers and end users. For example, in Japan, our distribution partner, Gunze Medical, purchases products from us and is responsible for sales to the end users for the approved indications of use and at the prevailing reimbursement rate for the product.

Coverage and Reimbursement

With the exception of government accounts, most purchasers of our products include physicians, hospitals, or ambulatory surgery centers ("***ASCs***") that rely on reimbursement by third-party payers. Accordingly, our growth substantially depends on adequate levels of third-party reimbursement for our products from these payers. Third-party payers have historically been sensitive to the cost of products and services and are increasingly seeking to implement cost containment measures to control, restrict access to, or influence the purchase of health care products and services. In the U.S., such payers include U.S. federal healthcare programs (e.g., Medicare and Medicaid), private insurance plans, managed care programs, and workers' compensation plans. Federal healthcare programs have prescribed coverage criteria and reimbursement rates for medical products, services, and procedures. Similarly, private, third-party payers have their own coverage criteria and negotiate reimbursement amounts for medical products, services, and procedures with providers. In addition, in the U.S., an increasing percentage of insured individuals are receiving their medical care through managed care programs (including managed federal healthcare programs) which monitor and may require pre-approval of the products and services that a member receives. Ultimately, however, each third-party payer determines whether and on what conditions they will provide coverage for our products, and such decisions often include each payer's assessment of the science and efficacy of the applicable product.

A portion of our products is purchased by U.S. government accounts (e.g., the VA and the Public Health Service, including the Indian Health Service), which do not depend on reimbursement from third-party payers. In order for us to be eligible to have our products purchased by such federal agencies and paid for by the Medicaid program, federal law requires us to participate in the VA Federal Supply Schedule ("***FSS***") pricing program.

Medicare Coverage

The largest third-party payer in the United States is the Medicare program, which is a federally-funded program that provides healthcare coverage for senior citizens and certain disabled individuals. The Medicare program is administered by the Centers for Medicare and Medicaid Services ("***CMS***"), an agency within the U.S. Department of Health and Human Services ("HHS"). Medicare Administrative Contractors ("***MACs***") are private insurance companies that serve as agents of CMS in the administration of the Medicare program and are responsible for making coverage decisions and paying claims for the designated Medicare jurisdiction. There are seven Part A/B MACs in the U.S., which cover 12 unique geographical jurisdictions. Each MAC also has its own standards and process for determining coverage and reimbursement for a procedure or product. Private payers often follow the lead of governmental payers in making coverage and reimbursement determinations. Therefore, achieving favorable Medicare coverage and reimbursement is usually a significant gating factor for successful adoption of a new product or clinical application by private payers.

The coverage and reimbursement framework for products under Medicare is determined in accordance with the Social Security Act and pursuant to regulations promulgated by CMS, as well as the agency's coverage and reimbursement guidance. In some cases, CMS does not specify coverage, leaving each of the MACs to determine whether and on what conditions they will provide coverage for the product. Such decisions are based on each MAC's assessments of the science and efficacy of the applicable product. As noted below under the heading "Research and Development," we have devoted significant resources to clinical studies to provide data to the MACs, as well as other payers, in order to demonstrate the clinical efficacy and economic effectiveness of our tissue technologies.

For Medicare reimbursement purposes, our EPIFIX, EPICORD and EPIEFFECT allografts are classified as "skin substitutes." Current reimbursement methodology varies between the hospital outpatient department ("***HOPD***") and ASC setting versus the physician office. Currently, within the HOPD and ASC places of service, skin substitutes are reimbursed under a "packaged" or "bundled" methodology that provides a single payment for both the application of the product as well as the product itself. CMS classifies skin substitutes into low cost or high cost groups. Our EPIFIX, EPICORD and EPIEFFECT products are all reimbursed under the high cost bundle in these settings. The national HOPD average packaged ("bundled") rate for our EPIFIX and EPICORD allograft products was $1,715 in 2021, $1,749.26 in 2022, $1,725 in 2023, and $1,738 in 2024. The national HOPD average packaged ("bundled") rate for our EPIFIX, EPICORD and EPIEFFECT products in 2025 is $1,829.23. CMS assigns lower national rates to the ASC to reflect a less resource-intensive place of service. Revenue in the ASC setting constitutes less than 1% of the Company's annual net sales. Medicare payments for most items and services, including EPIFIX and EPICORD sheet products, have been subject to sequestration reductions of approximately 2% periodically from 2013.

Medicare reimbursement in the physician office and associated care settings has been under increased scrutiny over the last couple of years and has led to changes in the manner in which products qualify for coverage and are reimbursed. We expect additional reimbursement changes over the course of 2025 associated with skin substitutes. Beginning in 2022, CMS announced plans to potentially change the reimbursement mechanism for skin substitutes in the physician office setting but has not proposed or enacted any national changes to the rules for these products to date. Over the last several years, a combination of rapidly escalating prices and volumes in the industry has resulted in Medicare spending on skin substitutes to increase dramatically, with annual spending in 2020 of about $500 million to a monthly run-rate of over $1 billion per month by the end of 2024.

In response to this dramatic increase in Medicare spending, the MACs together released a proposed Local Coverage Determination ("***LCD***") in April 2024 that was further refined and finalized in November 2024. This policy, which is scheduled to become effective April 13, 2025 includes lists of skin substitute products which would explicitly be eligible for coverage and those which would not, based upon prospective, peer-reviewed randomized, controlled trials ("***RCTs***").

The Company's EPIFIX and EPICORD products are recognized in the document for having sufficient evidence for coverage, with EPIFIX listed as covered for DFUs and VLUs and EPICORD covered for DFUs. EPIEFFECT, the Company's other primary product for the Wound markets, will not be covered under this policy initially. We are currently enrolling an RCT for EPIEFFECT designed to generate and publish the requisite evidence for coverage in the future.

Private Payers

We have devoted considerable resources to clinical trials to support coverage and reimbursement of our products. An increasing number of private payers reimburse for EPIFIX and EPICORD in the physician office, the HOPD and the ASC settings, and we have complete national commercial coverage for the use of EPIFIX in the treatment of DFUs. Additionally, EPIEFFECT has also started to receive private reimbursement in certain regions of the U.S. and we are focused on continuing to increase the number of covered lives eligible for this product in the future, most notably through the completion of a well designed and powered RCT that we are currently enrolling.

Coverage and reimbursement vary according to the patient's health plan and related benefits. The majority of health plans currently provide coverage for EPIFIX and EPICORD for the treatment of DFUs, and many include treatment of VLUs. MIMEDX has secured payer coverage for over 300 million covered lives, allowing a significant number of patients access to our products. Information contributing to the coverage determination included a third-party technical brief (by the Agency for Healthcare Research and Quality ("***AHRQ***")) that evaluated a number of skin substitutes for treating chronic wounds, in which EPIFIX was noted to have the most Randomized Controlled Trials, a low risk of overall study bias, and statistically significant findings.

We have established and continue to grow a reimbursement support group to provide providers and patients with accurate coverage and reimbursement information regarding our products, and plan to continue investing in clinical data supportive of coverage for our products in additional clinical areas of use.

Hospital Use

Products administered in the hospital inpatient setting are bundled when submitted as part of the hospital's claim under a diagnosis-related group ("***DRG***"). In these cases, we continue to educate the hospital that our products are cost-effective, and have the potential to improve patient outcomes and reduce the length of stay. We are working to develop additional health economic data to support this effort. As noted above, the ability to sell products in a hospital is dependent upon demonstrating to the hospital the product's efficacy and cost effectiveness.

Seasonality

Revenues during our fourth quarter tend to be stronger than other quarters because many hospitals increase their purchases of our products during the fourth quarter to coincide with the end of their budget cycles in the United States. Satisfaction of patient deductibles through the course of the year also results in increased revenues later in the year. In general, our first quarter usually has lower revenues than the preceding fourth quarter, the second and third quarters have higher revenues than the first quarter, and the fourth quarter revenues are the highest in the year.

Customer Concentration

For the years ended December 31, 2024, 2023, and 2022, our top ten customers accounted for 20%, 20% and 19%, respectively, of our net sales, and net sales to all U.S. government accounts comprised approximately 1%, 2% and 2%, respectively, of our net sales.

Competition

Due to lower barriers to entry in the Section 361 HCT/P regulated market, competition is intense in the skin substitute market, particularly among human derived products and subject to new entrants and evolving market dynamics. Companies within the industry compete on the basis of price, ease of handling, logistics and efficacy. Another important factor is third-party reimbursement, which is difficult to obtain as it is a time-consuming and expensive process. We believe our success in obtaining third-party reimbursement, our strong position with group purchasing organizations, and the established clinical evidence for our products are competitive advantages.

In February 2020, the AHRQ published a technology assessment analyzing Skin Substitutes for Treating Chronic Wounds. AHRQ conducted a literature search yielding 164 studies and 81 Supplemental Evidence and Data for Systematic Reviews ("***SEADs***") submissions. Only 22 RCTs met the inclusion criteria to be reviewed in the AHRQ analysis, and out of the 22 RCTs MIMEDX had six RCTs included in the final brief. Of the 22 studies reviewed, only 12 were assessed as low risk of bias, of which five were MIMEDX RCTs. This important government assessment highlights our commitment to providing unbiased level 1 clinical evidence in advanced wound treatment. This dedication to elevating the standard of care is further underscored by the fact that the AHRQ points out in its assessment that MIMEDX was the only entity to provide two studies out of the 22 evaluated that performed a subgroup analysis of patients with DFUs that received adequate debridement. Both studies reported an increase in wounds healed with adequate debridement.

AWC therapies employ technologies to aid in wound healing in cases where the wound is chronic and healing progress has stalled or stopped. The primary competitive products in the skin substitutes category include, among others, placental-tissue allografts, tissue-engineered living skin equivalents, porcine-, bovine- and fish skin-derived xenografts and collagen matrix products.

Our main publicly-traded competitors in the skin substitute market include Integra LifeSciences Holdings Corporation, Organogenesis, Inc., and Smith & Nephew plc, which sell a variety of AWC products, including skin substitutes and placental tissue allografts. In addition, the overall market is competitive, with a large number of other, oftentimes privately-held competitors that compete regionally and nationally, primarily in the physician office and associated care settings due to the historical Medicare reimbursement and pricing dynamics that resulted in significant growth of Medicare expenditures for skin substitutes.

Government Regulation and Compliance

The products we sell are regulated by the FDA in the United States. The majority of the products currently manufactured and processed by the Company are derived from human tissue. Generally, our products currently sold in the United States are regulated as Human Cells, Tissues, and Cellular and Tissue - Based Products (***"HCT/Ps"***), and are subject solely to Section 361 of the Public Health Service Act (***"Section 361"***) and related regulations, which do not require pre-market clearance or approval by the FDA. We do not currently sell in the United States those cellular and tissue-based products considered to be drugs, devices, and/or biological products (***"Section 351 HCT/Ps"***) subject to licensure under Section 351 of the Public Health Service Act (***"Section 351"***) and related regulations. Section 351 HCT/Ps are regulated as biological products, and, in order to be lawfully marketed in the United States, require FDA pre-market approval.

Beginning in 2024, we began commercializing a xenograft product, HELIOGEN, which is a 510(k) cleared product manufactured by Regenity Biosciences, a contract manufacturer. As a result, MIMEDX assumes FDA regulatory responsibilities associated with medical device distribution including complaint handling and medical device reporting as well as certain state requirements for medical device distribution.

Tissue Products

The FDA requires each HCT/P establishment to register and establish that its product meets the requirements to qualify for regulation solely under Section 361. To be a Section 361 HCT/P, a cellular or tissue-based product generally must meet all four of the following criteria (fully set forth in 21 CFR Part 1271):

- it must be minimally manipulated;
- it must be intended for homologous use;
- its manufacture must not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agent; and
- it must not have a systemic effect and must not be dependent upon the metabolic activity of living cells for its primary function.

Certain amniotic and other birth tissues are considered cellular and tissue-based articles and are therefore eligible for regulation solely as a Section 361 HCT/P depending on whether the specific product at issue and the claims made for it are consistent with the criteria set forth above. HCT/Ps that do not meet these criteria are subject to more extensive regulation as drugs, medical devices, biological products, or combination products.

Products Regulated Solely as Section 361 HCT/Ps

The FDA has specific regulations governing HCT/Ps, including some regulations specific to Section 361 HCT/Ps, which are set forth in 21 CFR Part 1271. All establishments that manufacture Section 361 HCT/Ps must register and list their HCT/Ps with the FDA's Center for Biologics Evaluation and Research within five days after commencing operations. In addition, establishments are required to update their registration annually in December or within 30 days of certain changes and submit changes in HCT/P listing at the time of or within six months of such change.

The regulations in 21 CFR Part 1271 also require establishments to comply with donor screening, eligibility and testing requirements, and CGTP to prevent the introduction, transmission and spread of communicable diseases. The CGTP govern, as may be applicable, the facilities, controls, and methods used in the manufacture of all HCT/Ps, including processing, storage, recovery, labeling, packaging, and distribution of Section 361 HCT/Ps. CGTP require us, among other things, to maintain a quality program, train personnel, control, and monitor environmental conditions as appropriate, control and validate processes, properly store, handle and test our products and raw materials, maintain our facilities and equipment, keep records and comply with standards regarding recovery, pre-distribution, distribution, tracking and labeling of our products, and complaint handling. 21 CFR Part 1271 also mandates compliance with adverse reaction and CGTP deviation reporting and labeling requirements.

The FDA conducts periodic inspections of HCT/P manufacturing facilities, and contract manufacturers' facilities, to assess compliance with CGTP. Such inspections can occur at any time, with or without written notice, at such frequency as determined by the FDA in its sole discretion. To determine compliance with the applicable provisions, the inspection may include, but is not limited to, an assessment of the establishment's facilities, equipment, finished and unfinished materials, containers, processes, HCT/Ps, procedures, labeling, records, files, papers and controls required to be maintained under 21 CFR Part 1271. If the FDA were to find serious non-compliant manufacturing or processing practices during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations, financial condition, and cash flows.

2017 FDA Guidance and Transition Policy for HCT/Ps

In November 2017, the FDA released four guidance documents that, collectively, the agency described as a "comprehensive policy framework" for applying existing laws and regulations governing regenerative medicine products, including HCT/Ps. One guidance document in particular, "*Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue – Based Products: Minimal Manipulation and Homologous Use – Guidance for Industry and Food and Drug Administration Staff*," offered important clarity.

The guidance documents confirmed that sheet forms of amniotic membrane generally are appropriately regulated as solely Section 361 HCT/Ps when intended for use as a barrier or covering. We continually evaluate our marketing materials for each of our products to align with FDA guidance.

In March 2024, the FDA issued a determination letter in connection with the RFD process related to AXIOFILL, a human-derived particulate wound dressing. In the letter, FDA reaffirmed its position that AXIOFILL does not meet the regulatory classification requirements under Section 361. In response to the RFD determination letter, the Company has filed suit in the U.S. District Court for the Northern District of Georgia and intends to exhaust all legal options available, given the arbitrary and capricious manner in which FDA is regulating like-kind products. Notably, while these proceedings are taking place, the Company is permitted to continue marketing AXIOFILL.The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that the Company has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, such as issuing an FDA Form 483 notice of inspectional observations; sending a warning letter or untitled letter; issuing an order of retention, destruction, or cessation of marketing; imposing civil money penalties; suspending or delaying issuance of approvals; requiring product recalls; imposing a total or partial shutdown of production; withdrawing approvals or clearances already granted; pursuing product seizures, consent decrees or other injunctive relief; and criminal prosecution through the Department of Justice ("***DOJ***").

FDA Post–Market Regulation

Tissue processors regulated solely under Section 361 are still required to register as a tissue establishment with the FDA. As a registered tissue establishment, we are required to comply with regulations regarding labeling, record keeping, donor eligibility, screening, and testing. We are also required to process the tissue in accordance with established CGTP, as well as report any deviations from core CGTP requirements or adverse reactions caused by a possible transmission of an infectious disease attributed to our tissue. Our facilities are also subject to periodic inspections to assess our compliance with the regulations.

Other Regulation Specific to Tissue Products

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

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

Section 1: General Information

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 8900 NE 48th Street

City: Kansas City State: MO Zip: 64141

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 816-200-5200 Website: www.mckesson.com

Name of Designated Representative (DR): Frank Cardenas

Licensing Company Email: mckessonlicensing@mckesson.com DR Email: frank.cardenas@mckesson.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

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

Provide explanation below:

See attached

Original Signature (electronic, copies or stamps not accepted)

11 OCT 2025

Date

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its wholly owned subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 100 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. We have limited this summary to disciplinary actions taken against these facilities during the time frame specified in the question or the last six years in accordance with McKesson Corporation's Records and Information Management (RIM) Policy. ***The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.***

On January 7, 2020, **McKesson Corporation** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

On January 14, 2020, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,000 was imposed and paid on January 14, 2020.

On February 20, 2020, in response to the DEA Settlement, McKesson Corporation entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 29, 2020, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of $1,150 was imposed and paid on July 1, 2020.

On April 20, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,125 was imposed and paid on April 20, 2021.

On May 05, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Maine Board of Pharmacy, regarding its Roseville, CA distribution center, in relation to the late reporting of a disciplinary action that was imposed by the Colorado Board of Pharmacy, for failure to report a change of designated representative within the required timeframe. A $500 civil penalty/fine was paid on 5/7/2021.

On May 27, 2021, **McKesson Corporation** entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the

Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

On June 6, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on June 8, 2021.

On June 15, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $3000.00 was imposed and paid on June 15, 2021.

On June 23, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $125 was imposed and paid on June 23, 2021.

On October 1, 2021, **McKesson Corporation** ("McKesson") entered into a non-disciplinary agreement with the Connecticut Department of Consumer Protection, regarding its Memphis, TN distribution center. The agreement resolves allegations that, from January 2015 – January 2021, McKesson sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration. McKesson made no admission of liability and there were no findings of any violation of law. A monetary penalty of $4,500 was imposed.

On October 14, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a Settlement Agreement with the Ohio Board of Pharmacy (the "WCH Ohio Settlement"). The WCH Ohio Settlement applies to the McKesson distribution center located in Washington Court House, Ohio. The Ohio Settlement also resolved allegations of suspicious order reporting violations related to sales occurring between 2011 and 2017. Under the terms of terms of the WCH Ohio Settlement, there were no findings of any violation of law and McKesson made no admissions to the same. McKesson was subject to a reprimand and a fine of twenty-thousand dollars ($20,000).

On December 20, 2021, **McKesson Corporation** entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

On January 18, 2022, **McKesson Medical-Surgical Inc**, entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on January 18, 2022.

On March 24, 2022, **McKesson Corporation** and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and there are no findings of any violation of state or federal laws.

On May 20, 2022, **McKesson Medical Surgical, Inc**.'s Urbancrest, Ohio facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On July 19, 2022, **McKesson Medical Surgical, Inc**.'s Urbancrest, Ohio facility entered into a settlement agreement with the Alabama Board of Pharmacy. The Alabama discipline was in response to discipline the facility received from the Ohio Board of Pharmacy in 2021 McKesson paid a $3,000 fine under the Alabama settlement.

On September 16, 2022, **McKesson Medical-Surgical Inc.'s** Leetsdale, PA facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Roseville, CA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Complaint from November 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Corporation**'s Aurora, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Complaint from September 2022. The Administrative Complaint is a result of alleged failure comply with certain licensing requirements required to maintain a license in violation of Rule 680-X-2.23(g)(3). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Manteno, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Compliant from September 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On April 14, 2023, **McKesson Corporation**'s Memphis, TN facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023, upon compliance with the Deferral Agreement and payment of $4,000.00 costs to the Board.

On July 10, 2023, **McKesson Medical-Surgical Inc.**'s Bethlehem, PA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an alleged discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $5,000.00 costs to the Board.

On July 22, 2023, **McKesson Corporation**'s Santa Fe Springs, CA distribution center entered into a Consent Order with the Alabama Board of Pharmacy. The Consent Order constitutes reciprocal disciplinary action that was based entirely on a February 22, 2022, Decision and Order from the California Board of Pharmacy. There were no new facts giving rise to the Alabama Consent. Your office was notified of the California Order on or about 03/25/2022. Pursuant to the terms of the Alabama Consent, McKesson agreed to pay a fine of $25,000.

On August 29, 2023, **McKesson Medical-Surgical Inc.**'s Hanover Park, IL's facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with failing to provide notice of a change of ownership on a permit that the Board itself has deemed unnecessary. Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023, upon compliance with the Deferral Agreement and payment of $4,000 costs to the Board.

On April 12, 2024, **McKesson Corporation**'s Duluth, GA distribution center entered into a Public Consent Agreement with the Georgia State Board of Pharmacy. McKesson Corporation was disciplined for failure to maintain prescription drugs securely and assessed a fine of $10,000.

On May 29, 2024, **McKesson Medical-Surgical Inc**.'s Jacksonville, FL facility entered into a Consent Agreement with the Georgia State Board of Pharmacy due to the facility changing ownership and updating their licensure prior to receiving board approval. Under O.C.G.A § 26-4-40, the Georgia State Board of Pharmacy is authorized to deny Applicants application for licensure due to changing ownership without Board Approval. Based on the Consent Agreement, McKesson Medical-Surgical Inc shall submit a payment of One-Thousand Seven-Hundred Dollars ($1,700) for the violation. The Board agrees to grant the ownership change and licensure update once the terms and conditions of the agreement are met.

On August 29, 2024, the Ohio Board of Pharmacy issued a Final Order to **McKesson Corporation** for activities that occurred at McKesson's former distribution center previously located in Washington Courthouse, OH for purchases of dangerous drugs from an unlicensed entity from July 2019 to April 2021. The Board imposed a monetary fine in the amount of $2,750.00.

On August 30, 2024, **McKesson** (in addition to Cardinal Health, Inc. and Cencora, Inc. (f/k/a AmerisourceBergen Corporation) (collectively, the "Distributors")) has agreed to enter into a settlement agreement with third party payor ("TPP") plaintiffs to resolve certain opioid-related claims.

On September 12, 2024, the Idaho Board of Pharmacy ("BOP") entered into a Stipulation and Consent Order with **McKesson Medical-Surgical Inc.** ("MMS") whereby the parties mutually agree to settle two separate matters from MMS' Chino, CA and Roseville, CA distribution centers in 2020 and 2021 involving a deficient Designated Representative application and failure to timely renew its license application, respectively. The parties agree that sufficient mitigating factors exist (including the COVID-19 pandemic and various stay-at-home orders) to warrant resolution of these matters via the Stipulation and Consent Order without an admission of guilt by MMS and whereby the Stipulation and Consent Order requires MMS to pay a fine to the BOP in the amount of $6,000 and to reimburse the BOP for investigative costs in the amount of $5,200.

On September 25, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of One Thousand Five Hundred Dollars ($1,500) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

On November 14, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of Five Thousand Dollars ($5,000) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

On March 19th, 2025, Maryland State Board of Pharmacy ("MBOP") and **McKesson Medical-Surgical, Inc.** ("MMS") entered into a Pre-Charge Consent Order ("Consent Order") after MMS self-reported distributing prescription products into Maryland from its Distribution Center in Suwanee, GA without the required wholesale distributor permits. An MMS internal investigation revealed that approximately 400 prescription orders were distributed without the permit between September 2019 and September 2024 due to a miscoding error. MMS has since updated its product classifications and implemented additional checks. As part of the Consent Order, MMS agreed to pay a $5,000 fine to the MBOP and MBOP agreed to process MMS' pending wholesale permit application.

On April 22, 2025, the Nevada State Board of Pharmacy ("NV BOP") issued a citation and fine order to **McKesson Medical-Surgical, Inc.** ("MMS") distribution center located in Chino, CA for unprofessional conduct. MMS erroneously shipped drugs to a hospice patient's home without a legitimate request, due to a mis-pick error. This action violated NAC 639.945(1)(i) and NRS 639.210(4), posing serious risks to patient safety. The NV BOP assessed an administrative fine of $500 to MMS for the incident.

On August 20, 2025, the Michigan Board of Pharmacy issued a Consent Order and Stipulation resolving disciplinary action against **McKesson Corporation** distribution center located in Holt, MI, resulting in a fine of $1,000. The Michigan Board of Pharmacy found violations of Mich Admin Code R 338.3141(1) and MCL 333.17768(2)(e), which require effective controls against theft and diversion of controlled substances.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: This facility is not yet operational

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Virginia

Parent Company (if any): McKesson Medical-Surgical Holdings Inc - ultimate owner McKesson Corporation publicly traded

Corporation Name: McKesson Medical-Surgical Inc.

Mailing Address: 6555 N State Highway 161

City: Irving State: TX Zip: 75039

Telephone: 972.446.4800 Email: mckessonlicensing@mckesson.com

Contact Person Name: Daniel Wright

Date of SEC Registration: 07/07/1994 | SEC Registration Number: 2417015 | Stock Exchange Symbol: MCK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

McKesson Medical-Surgical Inc.

Facility Name

Daniel Wright

Print Name of Authorized Person Submitting Application

D. M

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

11 OCT 2025

Date

Board Use Only	Date Received: 11/10/25	Amount: $1,000.00

McKesson Medical-Surgical Inc. – Additional Details

Virginia company incorporated on February 27th, 1980.

Applicant:

McKesson Medical-Surgical Inc.
8900 NE 48th Street
Kansas City, MO 64141
Clay County
Phone: (816) 200-5200
FEIN: 94-2640465

Parent Company:

McKesson Medical-Surgical Holdings Inc.
9954 Mayland Drive, Suite 4000, Richmond, VA 23233
FEIN: 13-3734754

Corporate Officers:

Stanton J. McComb, President, Director
9954 Mayland Drive, Suite 4000, Richmond, VA 23233, Director

Gregory S. Keyes, Executive Vice President, Treasurer
9954 Mayland Drive, Suite 4000, Richmond, VA 23233

Steven Tarantino III, Vice President
9954 Mayland Drive, Suite 4000, Richmond, VA 23233

Daniel R. Wright, Vice President
9954 Mayland Drive, Suite 4000, Richmond, VA 23233

Saralisa C. Brau, Secretary
6555 State Highway 161 Irving, TX 75039

Designated Representative:

Frank Cardenas, Sr. Manager, Operations
8900 NE 48th Street
Kansas City, MO 64141
Phone: 816-668-9510
Email: frank.cardenas@mckesson.com

Application Contact:

Danna Sturgill, Senior Regulatory Specialist
Email: mckessonlicensing@mckesson.com
Phone: 714-470-8144

Description of Operation

Description of operation
Hours of Operation: M-F 24 Hours
Type of Products: Rx Drugs, Rx Devices, OTC Drugs, Medical Supplies and Equipment
Type of Customers: Practitioners, Hospitals, Clinics, Wholesalers & Pharmacies

Corporate Officers:

Name	Title	Work Address	Work Phone	Ownership
Stanton J. McComb	President; Director	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-553-2311	0%
Gregory S. Keyes	Vice President, Treasurer, Director	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	502-552-7416	0%
Saralisa C. Brau	Secretary	6555 State Highway 161 Irving, TX, 75039	202-904-7031	0%
Steven Tarantino III	Vice President	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-640-0035	0%
Daniel R. Wright	Vice President	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	708-466-7620	0%

Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure, or distribution is prohibited.

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

August 21, 2025

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2025082122217749

McKesson Medical-Surgical Inc. located at 8900 NE 48th Street, Kansas City, MO 64141 is a wholesale distributor of prescription drugs, devices, over the counter medications and medical supplies and equipment to the primary care and extended care markets.

The facility is approximately 307,000 square feet. The entire facility is temperature controlled and utilizes the Vaisala Continuous Monitoring System to monitor temperature and humidity on 24/7 basis. The security system includes access-controlled gates and doors, electrified door hardware, video surveillance with interior and exterior IP cameras, intercom, and alarm monitoring including door contacts, motion and glass break detection, and audible sounder strobes for emergency notification of unauthorized egress. The system is monitored and serviced by Everon, who is also the installation vendor, and by the McKesson SOC located in Atlanta.

Hours of operations are Monday-Friday 24 Hours.

McKesson Medical-Surgical
9954 Mayland Drive, Suite 4000
Richmond, VA 23233

www.mckesson.com


Ownership
McKesson Corporation
Federal ID 94-3207296
6535 N. State Highway 161
Irving, TX 75039
McKesson Medical-Surgical Top Holdings Inc.
Federal ID 59-2280364
9954 Mayland Drive Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Holdings Inc.
Federal ID 13-3734754
9954 Mayland Drive Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Inc.
Federal ID 94-2640465
9954 Mayland Drive, Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Inc.
8900 NE 48th
Kansas City, MO 64161

State of Missouri
Division of Professional Registration
Drug Distributor

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2025047935
MCKESSON MEDICAL-SURGICAL, INC.
MCKESSON MEDICAL-SURGICAL, INC.
8900 NE 48TH
KANSAS CITY MO 64141
UNITED STATES

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Drug Distributor

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2025047935
Frank Jose Cardenas De La Paz

MCKESSON MEDICAL-SURGICAL, INC.
MCKESSON MEDICAL-SURGICAL, INC.
8900 NE 48TH
KANSAS CITY MO 64141
UNITED STATES

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

All	ADDRESS_1	ADDRESS_2	CITY	STATE	ZIP
PFIZER	BANK OF AMERICA	P.O. BOX 100539	ATLANTA	GA	30384
ABBOTT RAPID DX N AMERICA LLC	30 S KELLER ROAD	SUITE 100	ORLANDO	FL	32810
NESTLE HEALTHCARE NUTRITION IN	ATTN REBATE ANALYST 9THFLOOR	800 N.BRAND BLVD	GLENDALE	CA	91203

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/20/2025

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

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

PRODUCER	CONTACT NAME:	
Aon Risk Insurance Services West, Inc. Seattle WA Office 1420 Fifth Avenue Suite 3020 Seattle WA 98101-4030 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
McKesson Corporation and
all its subsidiaries
6555 North State Highway 161
Irving TX 75039 USA

COVERAGES **CERTIFICATE NUMBER:** 570113398855 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY319292	07/01/2025	07/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$2,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 319291 Self Insured for Phys Dam	07/01/2025	07/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			MWC31382625	07/01/2025	07/01/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N / A					E.L. EACH ACCIDENT	$1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

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

CERTIFICATE HOLDER

MCKESSON CORPORATION
6555 STATE HIGHWAY 161
IRVING TX 75039 USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West Inc.

Holder Identifier :

Certificate No : 570113398855

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG McKesson Medical-Surgical Inc. MDEG License # (if applicable) _____

Physical Address 8900 NE 48th Street

City Kansas City State MO Zip 64141

Mailing Address (if different from physical address) 8900 NE 48th Street

City Kansas City State MO Zip 64141

Telephone 816-200-5200 Website www.mckesson.com

Licensing Company Email danna.sturgill@mckesson.com and mckessonlicensing@mckesson.com

Section 2: Personal Information

First Frank Middle _____ Last Cardenas

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

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

Mailing Address 8900 NE 48th Street

City Kansas City State MO Zip 64141

Telephone [redacted] Email frank.cardenas@mckesson.com

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

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/19-Current	[redacted]	[redacted]	MO	[redacted]
From - To (MM/YY – MM/YY)			State	
02/18-02/19			MO	
From - To (MM/YY – MM/YY)			State	
01/17 - 02/18			MO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
McKesson Medical-Surgical Inc.			10/2019-Current	
Business Address		**City**	**State**	**Zip**
1405 N. Chouteau Trafficway		Kansas City	MO	64120
Phone	**Title**		**Number of Employed Hours**	
(816) 204-3300	Sr. Operations Manager		6+ years	
Description of Duties				
Oversee daily operations, see attached resume				

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

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

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

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

Continue on next page if additional space is needed.

FRANK CARDENAS
[redacted]

SUMMARY

An engaging, dynamic, and driven leader with robust experience advancing corporate operations, procurement prowess enhancing KPI's, customer service to accomplish rigorous targets for clients and company goals. Highly effective leader with a proven record of coaching high-performing teams and directing complex projects while optimizing efficiency, meeting project scope parameters, and bolstering client service delivery. Motivational leader able to employ detailed analysis, logistics, and operations knowledge to inspire the cost per line reduction and exceed internal DPMO targets. Possesses excellent communication, analysis, and technical skills. Has the capacity to quickly adapt to new processes to meet corporate standards or clientele needs.

PROFESSIONAL EXPERIENCE

McKesson, Kansas City, MO

Sr. Operations Manager October 2021 – Present

Organized departmental strategy on the Outbound Teams to enhance customer experience, productivity increase, and process improvements while evaluating financial and operational performance metrics to grow margin and monitor expenses.

- Created and implemented a new DPMO program for the DC, with threshold goals, error researching methods, performance communication, accountability, and a new QA process.
- Created a housekeeping SOP that contributed substantially to warehouse Bin Integrity and Safety metric overall.
- Created and executed a Lead/Trainer MTM (Move the Middle) project, bringing the Case Pick and Shipping teams to be the highest performance team in the DC level, performing now 30% more than they were previously.
- Developed a Training Matrix Program for every task, and department in the DC.
- Built a new 'webpage error' program for the DC, with a 4602's subprocess, replenish tool and accountability standards.
- Developed a Priority Route system to insure 100% of shipments done on time.
- Created a Supervisor Quarterly Program to drive performance, engagement, and ownership.

Warehouse Supervisor October 2019- October 2021

Reviewed and monitored standard operating procedures; completed monthly observations and recommended improvements to promote efficiency in distribution of products. Maintained attendance records while handling all disciplines. Ensured compliance with all company policies, procedures, safety rules, as well as all state and federal regulations. Monitored performance and productivity measures for the purpose of maximizing Operational excellence, which includes service, quality, and cost control. Maintained a solid working relationship with both internal and external customers, associates, and field service representatives. Ensured efficient working operation of warehouse systems and processes. Increased LUM team performance from a 75% to a 110%. Decreased OT from 25% to a 4.5% in a consistent basis.

AmerisourceBergen, Kansas City, MO

Warehouse Supervisor September 2018 – October 2019

Direct a team of 20 associates in a fast-paced dynamic environment. Directed workflow for optimum production. Observed associates monthly, providing coaching, training, mentoring and career direction. Responsible for 100% error free order completion each day. Utilized AS400 each day to evaluate operations performance levels, balance the workload and perform the necessary job functions.

- Created reports to track and monitor associate's daily performance and promote continuous improvement.
- Increased team's production in four months from 81% to 129%.
- Implemented process improvements reducing error rate from 5% to 1.5%/10K orders.
- Performed using a video observation program for associate feedback. I further utilized this program to video the best practices to serve as a training tool for all associates.
- Provided direction in discussing and creating development plans.
- Interact with customers in resolving delivery and order filling issues.
- Created new staging areas, route signs and loading process for this department, allowing this department to reach a year with 100% of departures on time.

Warehouse Lead August 2017 – September 2018

Developed a monthly recognition program focusing on the reduction of errors. Reduced errors from 4.34 errors per 10 thousand lines to 2.265. Developed the "tote to tote" study focusing on associate performance. Utilize AS400 to evaluate operation performance levels in each department and train supervisors and leads. Reduced expenses by implementing the "300 pick" concept. Collaborate daily with other departments regarding staffing shortages. Created RF training programs for new associates. Assisted in developing processes in the refrigerator focusing on the optimization of the associate's performance. Helped develop and deliver the "We Are One" culture within the four departments on the night shift.

EDUCATION

- Universidad Central Martha Abreu de las Villas, Cuba.
- Bachelor's Degree in Industrial Engineering 2010-2014
- Projects, publications, and awards:
  Projects of Logistic Strategy for the company of Electrical Construction of Villa Clara 2014. Cuba, linked and applied to different companies, published in 2013 in "Universidad Central" Evaluation of Investment Projects. 2015. Cuba
- Postgraduates:
  Courses about: Business management and administration, organizational behavior of business, general accounting and finance of business, developing and presenting the Project of Economic and Financial Analysis linked and applied to Agricultural Company during 2015.

SPECIAL SKILLS

- Bilingual (Spanish and English)
- Proficient in Microsoft Office Word, Excel, PowerPoint and other computing tools.
- Knowledge about logistics, accounting and finance, optimization, planning, management of production and services processes, organization of work.
- Good decision making and leadership
- Strong organizational and attention to detail.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic copies or stamps not accepted)

Oct/10/2025
Date

I, Frank Cardenas, **certify that as the MDEG Administrator for**

McKesson Medical-Surgical Inc.,

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

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

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

Frank Cardenas
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Oct/10/2025
Date

Board Use Only	Date Received: 11/20/25

Last Name	First Name	Worker Type	Company	Location ID	Work State
Eiken	Angela	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Nading	Ashley	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Sanders	Zachary	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Guein	Tara	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Cervantes	Alejandra	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Pierro	Jasmine	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Rich	Daniel	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Burchstead	Bradford	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bowen	Jacob	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Taylor	Daniel	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Pickett	Drake	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Laffler	Kevin	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Lipari	Stephen	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Libeer	Jerid	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Reedy	Sean	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Phelps	Andrea	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Henry	Bryant	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Harleman	Jordan	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Trabue	David	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Eagleson	Jessy	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Quackenbush	Dustin	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Daly	Dennis	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Hadley	Ursula	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ogaz	Maria	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Demartino	Tom	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Duku	Eunice	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bernal	Justin	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Wood	Christopher	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Tempel	Wayne	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Gilliland	Gregory	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Cox	Julie	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bedolla	Jacqueline	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Dominguez	Nicolasa	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Rogers	Lucila	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Cox	Wade	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Jaster	Dakota	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Tarkington	Kareen	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bauer	William	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Williams	Keith	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Campos	Eladio	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Valdez Gomez	Veronica	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Cardenas	Frank	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Harper	Ester	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri

Rosales	Thelma	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Chastain	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Richardson	Robert	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ochan	Robert	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Parker	Jamie	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bolten-Galan	Michelle	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Vazquez	Marlen	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Cruz	Jonathan	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Biersmith	Victor	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Titchenell	Deborah	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Hatles	Jackson	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ibrahim	Ismail	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Hakin	Abuhureira	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Shoop	Quaid	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Maurisio	Menson	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Aman	Tesfahans	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Wisemore	Jonabeth	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
White	Sarah	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Damian	Brenda	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Alvarado de Bocanegra	Jacqueline	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Page	Tiffany	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ehram	Herny	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Chavez	Maria E.	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Loyola	Printon	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Roby	Maidy	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Loyola	Kimberly	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ibuleco	Ramadhani	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Soumwei	Dison	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Munoz	Ramon	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Murisho	Abwe	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Kasongo	Solomon	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Lusungu	Dunia	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Mejia	Ivan	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bilombele	Buchunde	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Salinas Sierra	Maria	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Mmunga	Ramazani	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Mukandama	Mukucha	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Abidrabo	Reuben	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Carreon	Ricardo	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ochieng	Simon O.	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Cardenas	Omar	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Asifi	Mohammad Dawood	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Heck	James	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Loyola	Johnwen	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri

Martinez	Dianeyra	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Tarza	Emile	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Chambers	Jordan	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Chavez	Marlin	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Solorzano De Colato	Yeslin Suhey	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ra	Oby	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Navarro	Patricia	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Newby	Bradley	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Dakanno	Gavrin	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ngweji	Jolie	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Brittingham	Sara	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Semens	Annarihka	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Gomez	Mark	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Sumbu	Gamizoni	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bauer	Shawn	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Calderon	Luisa	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Mkangya	Albert	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Lulinda	Zawadi	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Thomas	Amelita	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Simons	James	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Semens	Jovany	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bradley	Ashlee	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Chavez	Keila	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Williams	Bryan	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Smith	Jonathan	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Perez	Mayren	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Sykes	Jnae	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Vasquez Perez	Wuilmer Antonio	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Cabe	Analyn	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Guzman	Omar	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Vasquez-Mendoza	Lorenzo	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Jocelyn	Tardy	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Fabián Suárez Sandoval	Yordy	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Kayumba	Sungura	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Chastain	Samantha	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Campbell	Andrew	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Chavez	Laura	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Henderson	Antonio	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Carrillo	Jasmin	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Dartilus	Jerry	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Simeus	Elson	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Ibarra	Jose	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Mubengwa	Faida	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Selevieux	Kilinda	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri

Meles	Simon	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Kabezama	Mhangaiko	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Kalenda	Jenovique	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Vijil Franco	Yeferson Omar	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Johnson	Junathian	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Waldag	Akoj	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Lulinda	Shukuru	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Rodriguez	Leyanis Rodriguez	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Mabon	Loren	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Frederick	Jean	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Joviane	Ester	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Espinoza	Laila	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Kazimi	Jamil	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Obe	Swedi	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Humphreys	Caleb	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Martinez Crespo	Osmany	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Kirkham	Kristopher	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Walls	DeAngelo	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Del Tránsito Vasquez Mendoza	Maria	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Aviles	Eliany	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Garcia	Yoanni	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Fontilus	Elinx	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Hernandez Sandoval	Juan	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Guerra	Jesus	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Carrasco Garcia	Thalia	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Shepheard	Mary	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Williams	Keith	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Bekru	Sara	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Davis	Mark	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Snapp	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Campos	Maria	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri
Rizvanovic	Refija	Employee	MGM McKesson Medical-Surgical Inc.	A003	Missouri

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): September 23, 2025

McKESSON CORPORATION
(Exact Name of Registrant as Specified in Charter)

Delaware	1-13252	94-3207296
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

6555 State Hwy 161
Irving, TX 75039
(Address of Principal Executive Offices, and Zip Code)

(972) 446-4800
Registrant's Telephone Number, Including Area Code

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.01 par value	MCK	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 **Regulation FD Disclosure.**

On September 23, 2025, in connection with its Investor Day, McKesson Corporation (the "Company") issued a news release updating Fiscal 2026 guidance and long-term targets. A copy of the Company's news release is attached hereto as Exhibit 99.1.

The Company will host an Investor Day beginning at 9:30 a.m. Eastern time today, which will be live-webcast and archived on the Company's Investor Relations website. To access the webcast and corresponding slide presentation, visit investor.mckesson.com/events-and-presentations.

The information contained in this item and item 9.01, including Exhibit 99.1, is furnished to the Commission, but shall not be deemed "filed" with the Commission for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act"), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, except as expressly stated in any such filing.

Item 9.01 **Financial Statements and Exhibits.**

(d) The following Exhibit 99.1 is furnished with this Current Report on Form 8-K.

Exhibit No.	Description
99.1	News release issued by the Company dated September 23, 2025
104	Cover Page Interactive Data File - the cover page iXBRL tags are embedded within the Inline XBRL document

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☐ Out-of-State

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

Section 1: General Information

Facility Name: NuSmile, Ltd

Physical Address: 3535 W 12th Street

City: Houston State: TX Zip: 77008

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 713-861-0033 Website: www.nusmile.com

Name of Designated Representative (DR): Leslie Gabriela Bratten

Licensing Company Email: licensing@nusmile.com DR Email: licensing@nusmile.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	■ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/10/2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: NuSmile, Ltd.

Address: 3315 W 12th Street City: Houston State: TX Zip: 77008

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): N/A

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 6: Partnership

Partnership Name: NuSmile, Ltd.

Mailing Address: 3535 W 12th Street

City: Houston State: TX Zip: 77008

Telephone: 713-861-0033 Email: licensing@nusmile.com

Contact Person Name: Diane Johnson Krueger

Section 7: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

NuSmile, Ltd.

Facility Name

Diane Johnson Krueger

Print Name of Authorized Person Submitting Application



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

12/10/2025

Date

Board Use Only	Date Received: 12/29/25	Amount: $1000 ch 100000 2510

From: REAL Solutions Group Licensing <licensing@realsolutionsgroup.co>
Sent: Monday, January 26, 2026 5:52 AM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Cc: licensing@nusmile.com
Subject: Re: Nevada Out-of-State Wholesaler Application-NuSmile, Ltd.

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

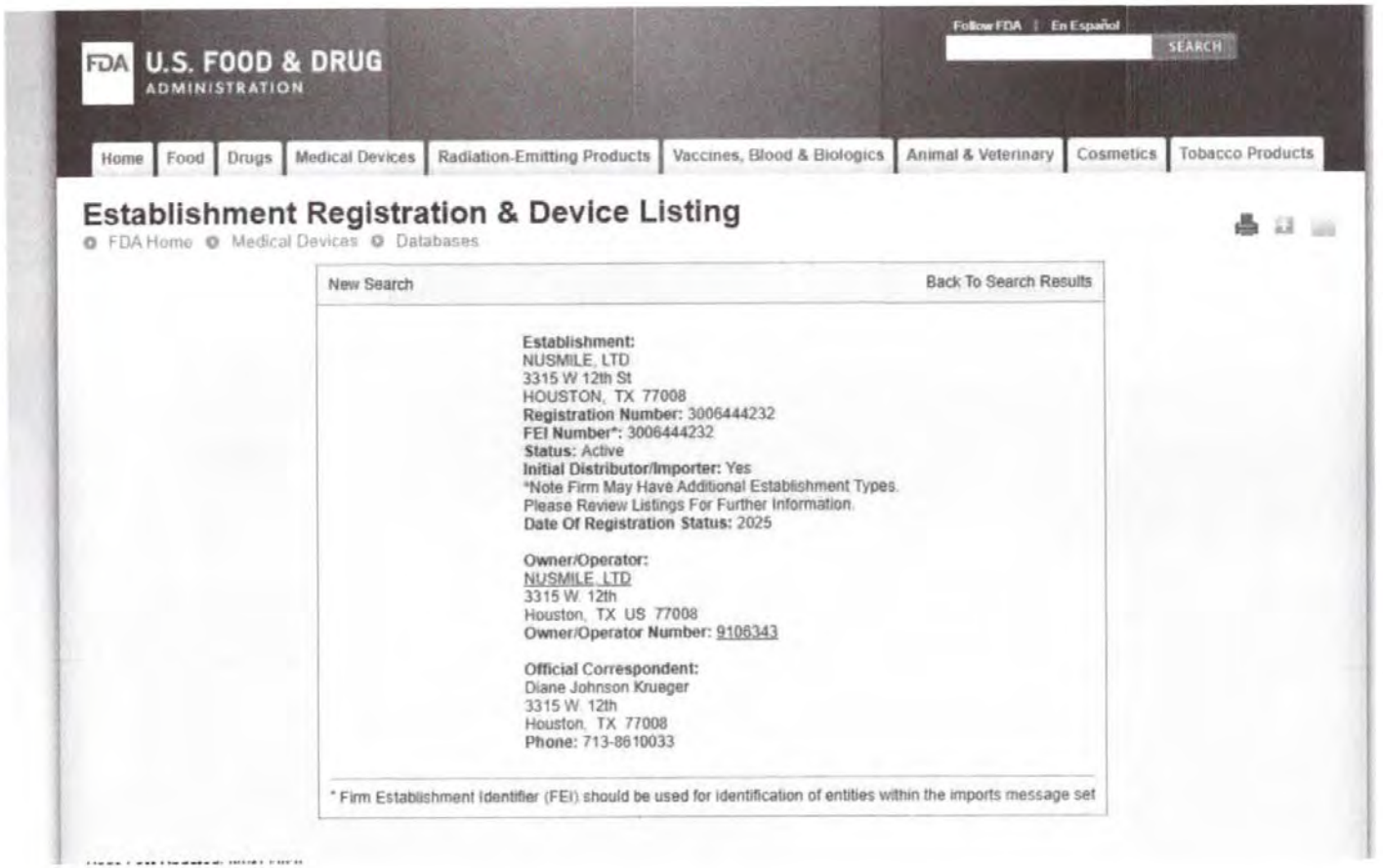
The facility is a single manufacturer for NuSmile, Ltd.

Thank you,
Shirl

On Fri, Jan 23, 2026 at 2:19 PM Maria Herrera <m.herrera@pharmacy.nv.gov> wrote:
Hello,

Is the facility a single manufacturer for NuSmile, Ltd?

Kind Regards,
Maria H.



FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

New Search | Back To Search Results

Establishment:
NUSMILE, LTD
3315 W 12th St
HOUSTON, TX 77008
Registration Number: 3006444232
FEI Number*: 3006444232
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
NUSMILE, LTD
3315 W. 12th
Houston, TX US 77008
Owner/Operator Number: 9106343

Official Correspondent:
Diane Johnson Krueger
3315 W. 12th
Houston, TX 77008
Phone: 713-8610033

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

NuSmile Ownership Organizational Chart



NuSmile Ownership Organizational Chart Pre 1/1/2026



NuSmile Ownership Organizational Chart Effective 1/1/2026



Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Limited Partnership for NuSMILE, LTD. (file number 800433629), a Domestic Limited Partnership (LP), was filed in this office on December 30, 2004.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on October 17, 2025.

Jane Nelson
Secretary of State

TEXAS
Health and Human Services

Texas Department of State Health Services

Jennifer A. Shuford, M.D., M.P.H.
Commissioner

December 2, 2025

Shirl Lamontagne
REAL Solutions Goup
licensing@realsolutionsgroup.co

CFN: 2266200
Lic.: 1003845
Type: 2503
File: 9445

Re: License Verification

Dear Shirl Lamontagne:

This letter shall serve as a verification of licensure for the following firm:
NUSMILE LTD
3535 W 12TH ST
HOUSTON, TX 77008

License No.	1003845
Type of license:	Device Manufacturer
Status of license:	Current
Date license issued:	11/25/2025
Date license expires:	09/22/2027
Disciplinary action:	None

The firm is in good standing as of the date of this letter.

If you have questions or need additional information, please contact me at 512-834-4503, via fax at (512) 834-6759, or email me at Justin.Arnold@dshs.texas.gov.

Sincerely,

Justin Arnold, MBA, RS
Medical Research Specialist
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Justin Arnold
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

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

NUSMILE LTD
3535 W 12TH ST
HOUSTON TX 77008

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

NUSMILE LTD

3535 W 12TH ST
HOUSTON, TX 77008

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

DEVICE MANUFACTURER

J. A. Hall, MD
Commissioner

License # 1003845
Expires: September 22, 2027

NON-TRANSFERABLE

515851

NUSMLTD-02 KVANDERLINDE

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 10/1/2025

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

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

PRODUCER	CONTACT NAME:	
Sebrite Agency, Inc. 1040 6th St S Hopkins, MN 55343-7802	PHONE (A/C, No, Ext): (800) 366-6466	FAX (A/C, No): (800) 767-6466
	E-MAIL ADDRESS: INFO@SEBRITEAGENCY.COM	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : The Hartford	11000
INSURED	INSURER B :	
Nusmile, LTD DBA Nusmile 3315 W 12th St Houston, TX 77008	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR			41SBANN8208	6/15/2025	6/15/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
	X Prof Liability						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 4,000,000
	X POLICY PROJECT LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	ANY AUTO			41SBANN8208	6/15/2025	6/15/2026	BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$ 3,000,000
	EXCESS LIAB CLAIMS-MADE			41SBANN8208	6/15/2025	6/15/2026	AGGREGATE	$ 3,000,000
	DED X RETENTION $ 10,000							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTHER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N/A						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Building			41SBANN8208	6/15/2025	6/15/2026	$1000 Ded	
A	Contents			41SBANN8208	6/15/2025	6/15/2026	$1000 Ded	

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

CERTIFICATE HOLDER

XXXXXXXXXX

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Samantha Bailey

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AGENCY CUSTOMER ID: NUSMLTD-02 KVANDERLINDE

LOC #: 1

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Sebrite Agency, Inc.		Nusmile, LTD DBA Nusmile 3315 W 12th St Houston, TX 77008
POLICY NUMBER		
SEE PAGE 1		
CARRIER	NAIC CODE	EFFECTIVE DATE: SEE PAGE 1
SEE PAGE 1	SEE P 1	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

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

NAME AND LOCATIONS
NuSmile, LTD DBA NuSmile Primary Crowns and DBA NuSmile Pediatric Crowns,
KE Dental

Policy #:41SBANN8208 6/15/25-6/15/26
Location 1: 3315 W 12th St, Houston, TX 77008
Building $3,390,800
Contents $1,685,900
Location 2: 3535 W 12th St, Houston, TX 77008
Contents:$647,400

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. B150084179

Application/License No. Applying for the license

NuSmile Ltd (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 3535 W 12th St Fl 3, Houston, TX 77008-6005 (Address of Applicant/Principal), as PRINCIPAL, and Old Republic Surety Company (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 18500 W Corporate Dr, Ste 170, Brookfield, WI 53045 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 9/30/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of September, 20 25.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Mary W Magnuson
Surety Company's Representative

Mary W Magnuson, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Kate Vandeln
Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint:

Mary Magnuson Of HOPKINS, Minnesota

Its true and lawful Attorney(s)-In-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, waste management bonds, hazardous waste remediation bonds or black lung bonds),*** as follows:

Effective Date: 09/30/2025

Bond Number: B150084179 Bond Amount: One Hundred Thousand Dollars $ 100,000.00

Principal Name: NuSmile Ltd

Obligee Name: NV State Board of Pharmacy, Nevada

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-In-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 30th day of September, 2025.

OLD REPUBLIC SURETY COMPANY

Assistant Secretary

President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 30th day of September, 2025, personally came before me, Alan Pavlic and Kevin J. Abitz, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

Notary Public

My Commission Expires: 09/28/2026

(Expiration of notary's commission does not invalidate this instrument)

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0401745

Signed and sealed at the City of Brookfield, WI this 30th day of September, 2025.

Assistant Secretary

ORSC 22282 (3-06)

SEBRITE AGENCY, INC.

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG NuSmile, Ltd. MDEG License # (if applicable) _____

Physical Address 3535 W 12th Street

City Houston State TX Zip 77008

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 713-861-0033 Website www.nusmile.com

Licensing Company Email licensing@nusmile.com

Section 2: Personal Information

First Leslie Middle Gabriela Last Bratten

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

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

Mailing Address 3535 W 12th Street

City Houston State TX Zip 77008

Telephone 713-861-0033 ext 305 Email licensing@nusmile.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Sharyland High School		08/04-05/07	
Address	**City**	**State**	**Zip**
1216 N Shary Road	Mission	TX	78572
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
The University of Texas Rio Grande Valley (UTRGV)		05/15-08/17	
Address	**City**	**State**	**Zip**
1201 W University Drive	Edinburg	TX	78539
Diploma/Degree obtained, if any			
Master of Business Administraion (MBA)			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/24-Present	[redacted]	[redacted]	TX	[redacted]
11/18-09/24			TX	
05/02-10/14			TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
NuSmile, Ltd.			01/18-Present	
Business Address		**City**	**State**	**Zip**
3535 W. 12th Street		Houston	TX	77008
Phone	**Title**		**Number of Employed Hours**	
713-861-0033	Director of Operations		14,000	
Description of Duties				
Provide strategic leadership & direction for operational functions including manufacturing, production planning, and supply chain. Ensures regulatory compliance & quality assurance in alignment with FDA, ISO 13485, and other applicable standards.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/18/25
Date

I, Leslie Gabriela Bratten, **certify that as the MDEG Administrator for**

NuSmile, Ltd.,

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

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

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

Leslie Gabriela Bratten
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/18/2025
Date

Board Use Only	Date Received: 12/29/25

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler NuSmile, Ltd

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 3535 W 12th Street

City Houston State TX Zip 77008

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 713-861-0033 Website www.nusmile.com

Licensing Company Email licensing@nusmile.com

Section 2: Personal Information

First Leslie Middle Gabriela Last Bratten

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

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

Mailing Address 3535 W 12th Street

City Houston State TX Zip 77008

Telephone 713-861-0033 ext 305 Email licensing@nusmile.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Sharyland Highschool		08/04-05/07	
Address	**City**	**State**	**Zip**
1216 N Shary Road	Mission	TX	78572
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
The University of Texas Rio Grande Valley (UTRGV)		05/15-08/17	
Address	**City**	**State**	**Zip**
1201 W University Drive	Edinburg	TX	78539
Diploma/Degree obtained, if any			
Master of Business Administraion (MBA)			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/24-Present	[redacted]	[redacted]	TX	[redacted]
11/18-09/24			TX	
05/02-10/14			TX	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
NuSmile, Ltd			01/18-Present	
Business Address		**City**	**State**	**Zip**
3535 W 12th Street		Houston	TX	77008
Phone	**Title**		**Number of Employed Hours**	
713-861-0033	Director of Operations		14,000	
Description of Duties				
Provide strategic leadership & direction for operational functions including manufacturing, production planning, and supply chain. Ensures regulatory compliance & quality assurance in alignment with FDA, ISO 13485, and other applicable standards.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/19/25
Date

I, Leslie Gabriela Bratten, **certify that as the designated representative for**

NuSmile, Ltd.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. Below I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs. DEVICES ONLY
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

3. X **I have been employed for at least 6,000 hours in pharmacy or with a wholesaler in a capacity related to the distribution of dental devices that do not contain a drug or any controlled substances.**

Continuation to #3 above - as clarification, NuSmile products do not contain drugs or any controlled substances.

Leslie Gabriela Bratten
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/19/25
Date

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

Leslie Gabriela Bratten

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/19/25

Date

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

State of Texas, ss. County of Harris

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

Original Signature

12/19/25

Date

Subscribed and Sworn to before me this 19th day of 2025.

Notary Public Signature

ASHLEY ANN COONER
Notary Public, State of Texas
Comm. Expires 06-19-2027
(Seal) Notary ID 13427692-3

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: NuSmile, Ltd.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3535 W 12th Street

City: Houston State: TX Zip: 77008

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 713-861-0033 Website: www.nusmile.com

Licensing Company Email: licensing@nusmile.com

Section 2: Personal Information

First: Diane Middle: Johnson Last: Krueger

Alias(es, nicknames, name changes, etc.): Diane Johnson

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

Mailing Address: 3535 W 12th Street

City: Houston State: TX Zip: 77008

Telephone: 713-861-0033 Email: licensing@nusmile.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Waltrip Senior High School		09/1970-01/1973	
Address	**City**	**State**	**Zip**
1900 W 34th Street	Houston	TX	77018
Diploma/Degree obtained, if any			
GED			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2021-Present	[redacted]	[redacted]	TX	[redacted]
From - To (MM/YY – MM/YY)			State	
01/1984-10/2021			TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
NuSmile, Ltd.			01/91-Present
Business Address	**City**	**State**	**Zip**
3535 W. 12th Street	Houston	TX	77008
Phone	**Title**		
713-861-0033	CEO/President		

Description of Duties

Diane Johnson Krueger, CEO and founder is a Certified Dental Technician. Mrs. Krueger leads the NuSmile organization with over 40 years of experience in dental products manufacturing and marketing.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic copies or stamps not accepted)

12/10/2025
Date

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

Diane Johnson Krueger

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/10/2025

Date

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

State of Texas, ss. County of Harris

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

Original Signature

12/15/2025

Date

Subscribed and Sworn to before me this 15th day of December.

Notary Public Signature

ASHLEY ANN COONER
Notary Public, State of Texas
Comm. Expires 06-19-2027
Notary ID 13427692-3
(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: NuSmile, Ltd.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 3535 W 12th Street

City: Houston State: TX Zip: 77008

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 713-861-0033 Website:

Licensing Company Email: licensing@nusmile.com

Section 2: Personal Information

First: Jason Middle: Last: Johnson

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

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

Mailing Address: 3535 W 12th Street

City: Houston State: TX Zip: 77008

Telephone: 713-861-0033 Email: licensing@nusmile.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Lamar Senior High School		09/1988-05/1991	
Address	**City**	**State**	**Zip**
3325 Westheimer Road	Houston	TX	77098
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Concordia University at Austin		01/1994-08/1997	
Address	**City**	**State**	**Zip**
11400 Concordia University Drive	Austin	TX	78726
Diploma/Degree obtained, if any			
Bachelor of Arts			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2007-Present	[redacted]	[redacted]	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
NuSmile, Ltd.			04/00-Present
Business Address	**City**	**State**	**Zip**
3535 W. 12th Street	Houston	TX	77008
Phone	**Title**		
713-861-0033	Executive Vice President		
Description of Duties			
Helps direct strategy of company. Oversees accounts payable and payroll functions of company.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/10/2025
Date

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

Jason Johnson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/10/2025

Date

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

State of Texas, ss. County of Harris

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

Original Signature

12/15/2025

Date

Subscribed and Sworn to before me this 15th day of December.

Notary Public Signature

ASHLEY ANN COONER
Notary Public, State of Texas
Comm. Expires 06-19-2027
(Seal) Notary ID 13427692-3

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site NuSmile, Ltd.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3535 W 12th Street

City Houston State TX Zip 77008

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 713-861-0033 Website www.nusmile.com

Licensing Company Email licensing@nusmile.com

Section 2: Personal Information

First Mark Middle _____ Last Binford

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

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

Mailing Address 3535 W 12th Street

City Houston State TX Zip 77008

Telephone 713-861-0033 Email licensing@nusmile.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Waltrip Senior High School		09/1972 - 05/1976	
Address	**City**	**State**	**Zip**
1900 W 34th Street	Houston	TX	77018
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
The University of Texas at Austin		09/1976 – 05/1981	
Address	**City**	**State**	**Zip**
110 Inner Campus Drive	Auston	TX	78712
Diploma/Degree obtained, if any			
Bachelor of Science in Chemical Engineering with Honors			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2016-Present	[redacted]	[redacted]	TX	[redacted]
8/2015-2/2016			TX	

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

Business Name			From - To (MM/YY – MM/YY)
NuSmile, Ltd.			05/14-Present
Business Address	**City**	**State**	**Zip**
3535 W. 12th Street	Houston	TX	77008
Phone	**Title**		
713-861-0033	COO		

Description of Duties

Operations, Marketing, Sales and Product Management professional with forty-five years' experience in specialty chemicals and engineered materials marketed to highly regulated industries. including oil & gas, specialty chemicals and dental products.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/11/2025
Date

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

Mark Binford

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/11/2025

Date

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

State of Texas, ss. County of Harris

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

Original Signature

12/15/2025

Date

Subscribed and Sworn to before me this 15th day of December.

Notary Public Signature

ASHLEY ANN COONER
Notary Public, State of Texas
Comm. Expires 06-19-2027
Notary ID 13427692-3

(Seal)

NuSmile, Ltd. Employee List

Andre Agustin
Xiomara Argueta
Anita Cardillo
Yarelis Esparza
Gerald Padilla
Julissa Perez
Hada Price
Rachel Ramirez
Karen Ramos
Fatima Rangel
Amy Segura
Karla Serna
Sirena Suriano
Samantha Yanez
Elena Espinoza
Zeina Hannoun
Jasmin Lara
Michael Loessberg
Nicole Alford
Zoe Kachantones
Erik Nordquist
Afsheen Anwar
Dremaceo Giles
David Hwang
Leslie Pantoja
Alexandra Plaza
Cassandra Alaniz
Isabella Oliveros
Jennifer Tremillo
Sabrina Munoz
Dimas Rodriguez
Maria Yata
Erin Binford
Jordan Kacal
Joanna Nevue
Preston Fontenot
Layne Ingram
Christopher Malzone

Priscilla Lara
Rachel Bynum
Alan Cantu
Jair Cantu
Ashley Cooner
Emmy Hernandez
Robert Lara
Bella Mia Padilla
Lezly Vazquez
Esmeralda Gonzalez
Victoria Macedo
Salma Nunez
Alba Orellana
Estella Robles
Reyna Rubio
Maria Salguero
Isela Torres
Diane Kreuger
Jason Johnson

4K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☑ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Ethicon Endo-Surgery, Inc.

Physical Address: 4545 Creek Rd

City: Cincinnati State: OH Zip: 45242

Mailing Address (if different from physical address): 4545 Creek Rd

City: Cincinnati State: OH Zip: 45242

Telephone: 513-337-7000 Website: www.Ethicon.com

Name of Designated Representative (DR): Emma Cinibulk

Licensing Company Email: ecinibul@its.jnj.com DR Email: ecinibul@its.jnj.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer (Virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers (Virtual)	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Emma Archer
Original Signature (electronic, copies or stamps not accepted)

11/3/2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: ~~Ohio~~ DE

Parent Company (if any): Johnson & Johnson

Corporation Name: Ethicon Endo-Surgery, Inc.

Mailing Address: 4545 Creek Rd

City: Cincinnati State: OH Zip: 45242

Telephone: 513-337-7000 Email: ecinibul@its.jnj.com

Contact Person Name: Emma Cinibulk

Date of SEC Registration: 09/24/1944 | SEC Registration Number: 0000200406 | Stock Exchange Symbol: JNJ

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: See Attachments A and B	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Attachment C	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) See Attachment E	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F		✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Ethicon Endo-Surgery, Inc.

Facility Name

Emma Cinibulk

Print Name of Authorized Person Submitting Application

Emma Cinibulk

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

11/3/2025

Date

Board Use Only	Date Received: 11/7/25	Amount: $1000 ck 2947

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back to Search Results

Establishment:
ETHICON ENDO-SURGERY, INC.
4545 CREEK RD
Cincinnati, OH 45242
Registration Number: 1527736
FEI Number*: 1527736
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
ETHICON ENDO-SURGERY, INC.[6]
4545 CREEK RD.
ML #39
Cincinnati, OH US 45242
Owner/Operator Number: 9010225[7]

Official Correspondent:
Emily Nesbill
4545 CREEK RD
ML #39
Cincinnati, OH 45242
Phone: 513-3371546

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set.

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9010225&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9010225&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=

Page Last Updated: 02/01/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9010225&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=

Attachment C

Corporation Information

Corporate Officers

Sandeep Makkar
WW President Endomechanical Energy

Funda Haine
VP Finance, MT Surgery

Lesley Traver
Vice President Quality and Compliance Ethicon

Parent Company

Johnson & Johnson
Percent ownership: 100

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ETHICON US, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3455002 8300

SR# 20251244574

Authentication: 203276977

Date: 03-26-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

See Attachment G

Regarding the Resident State License

The resident state licensing agency, the Ohio Board of Pharmacy (Board), does not require manufacturers of prescription devices to obtain a license. Enclosed is correspondence from the Board.

Kunkel, Lisa M.

From: LAKISHA.SCRUGGS@pharmacy.ohio.gov
Sent: Monday, February 26, 2024 3:38 PM
To: Kunkel, Lisa M.
Subject: FW: Prescription Device Licensing

EXTERNAL MESSAGE

Hello,

The State of Ohio Board of Pharmacy issues drug distributor licenses to entities for the manufacturing, distribution, etc. of dangerous drugs as defined in ORC 4729.01 (F) - http://codes.ohio.gov/orc/4729.01v1. We also issue licenses for entities that provide home medical equipment services directly to the public as defined in ORC 4752 (B) and (C) - http://codes.ohio.gov/orc/4752.01v1.

If the prescription medical device(s) does not contain a dangerous drug or meet the definition of home medical equipment, then a license is not required for the manufacturing, sale, or distribution of that device.

An entity can apply for licensure and must meet all drug distributor requirements.

STATE OF OHIO BOARD OF PHARMACY

Lakisha Scruggs
Licensing Coordinator
77 South High Street, 17th Floor, Columbus, Ohio 43215
Columbus Office – T: (614) 466-4143 | F: (614) 752.4836
Lakisha.Scruggs@pharmacy.ohio.gov
www.pharmacy.ohio.gov

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From: Kunkel, Lisa M. <lmkunkel@porziolicensing.com>
Sent: Monday, February 26, 2024 12:38 PM
To: PRX New.License <new.license@pharmacy.ohio.gov>
Subject: Prescription Device Licensing

Good afternoon,

Does your office require a virtual manufacturer of prescription devices located in Ohio to obtain a license? The prescription devices do not contain any drug products.

If no, can such a facility voluntary obtain a license with your office?

Thank you,

Attachment I

Liability Insurance

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/30/2024

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

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

PRODUCER
Marsh USA, LLC
1166 Avenue of the Americas
New York, NY 10036
Attn: newyork.certs@marsh.com - fax # 212-948-0500

24195 -J&Jr-GAWP-18-19

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Indemnity Ins Co Of North America	43575
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
JOHNSON & JOHNSON ET AL
ONE JOHNSON & JOHNSON PLAZA
ATTN: ERIN SHERIDAN
RISK MANAGEMENT
NEW BRUNSWICK, NJ 08933

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDO G48958369	03/01/2025	03/01/2026	EACH OCCURRENCE	$ 5,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 5,000,000
							MED EXP (Any one person)	$ 100,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$ 5,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						GENERAL AGGREGATE	$ 10,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$ N/A
								$
A	AUTOMOBILE LIABILITY			ISA H10825192	03/01/2025	03/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 10,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$
	DED [ ] RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			WLR C7263178A (AOS)	03/01/2025	03/01/2026	X PER STATUTE [ ] OTH-ER	
A	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A			WCU C72631869 (OH)	03/01/2025	03/01/2026	E.L. EACH ACCIDENT	$ 5,000,000
A	(Mandatory in NH)			WLR C72631742 (AZ, CA, MA)	03/01/2025	03/01/2026	E.L. DISEASE - EA EMPLOYEE	$ 5,000,000
A	If yes, describe under DESCRIPTION OF OPERATIONS below			RWC C72631821 (WI)	03/01/2025	03/01/2026	E.L. DISEASE - POLICY LIMIT	$ 5,000,000

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

CERTIFICATE HOLDER

Johnson & Johnson, et al
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
of Marsh USA Inc.

Michaela Grasshoff

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ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/5/2024

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

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

PRODUCER Marsh USA, LLC 1166 Avenue of the Americas New York, NY 10036 CN102448867-ALL-PL-21-22	**CONTACT NAME:** **PHONE (A/C, No, Ext):** / **FAX (A/C, No):** **E-MAIL ADDRESS:**	
	INSURER(S) AFFORDING COVERAGE	**NAIC #**
	INSURER A : Middlesex Assurance Company Ltd	10419
INSURED JOHNSON & JOHNSON ET AL ONE JOHNSON & JOHNSON PLAZA ATTN: ERIN SHERIDAN RISK MANAGEMENT NEW BRUNSWICK, NJ 08933	**INSURER B :**	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY CLAIMS-MADE ☐ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY ☐ PRO-JECT ☐ LOC OTHER:						EACH OCCURRENCE	$
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
							GENERAL AGGREGATE	$
							PRODUCTS - COMP/OP AGG	$
								$
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY ☐ SCHEDULED AUTOS HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB ☐ OCCUR **EXCESS LIAB** ☐ CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [N] N/A If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE ☐ OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	PRODUCT LIABILITY (US)			USPL9700001	01/01/2025	01/01/2026	EACH OCCURRENCE	10,000,000
							ANNUAL AGGREGATE	10,000,000

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

CERTIFICATE HOLDER

Johnson & Johnson, et al
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
of Marsh USA Inc.

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Johnson&Johnson

	Legal Entity Name	Main Office address
1	Abiomed, Inc.	22 Cherry Hill Drive, Danvers MA 01923, United States
2	Actelion Pharmaceuticals US, Inc.	1125 Trenton-Harbourton Road, Titusville, 1st Floor/B-Wing NJ 08560, United States
3	ALZA Corporation	700 Eubanks Drive, Vacaville CA 95688, United States
4	Ambrx, Inc.	10975 North Torrey Pines Road, La Jolla CA 92037, United States
5	AMO Sales and Service, Inc.	31 Technology Drive, Suite 200, Irvine CA 92618, United States
6	Anakuria Therapeutics, Inc.	1125 Trenton-Harbourton Road, Titusville NJ 08560, United States
7	AorTx, Inc.	150 Shoreline Drive, Redwood City CA 94065, United States
8	Aragon Pharmaceuticals, Inc.	10990 Wilshire Blvd. , Suite 440, Los Angeles CA 90024, United States
9	Auris Health, Inc.	150 Shoreline Drive, Redwood City CA 94065, United States
10	BeneVir BioPharm, Inc.	1330 Piccard Drive, Suite 101, Rockville MD 20850, United States
11	Biosense Webster, Inc.	31 Technology Drive, Suite 200, Irvine CA 92618, United States
12	Breethe, Inc.	1500 Joh Avenue, Halethorpe MD 21227, United States
13	Cerenovus, Inc.	325 Paramount Drive, Raynham MA 02767-0350, United States
14	Coherex Medical, Inc.	3598 West 1820 South, Salt Lake City UT 84104, United States
15	CoTherix Inc.	1125 Trenton-Harbourton Road, Titusville NJ 08560, United States
16	CrossRoads Extremity Systems, LLC	6423 Shelby View Drive, Suite 101, Memphis TN 38134, United States
17	CSATS, Inc.	1100 Olive Way, Suite 1150, Seattle WA 98101, United States
18	DePuy Mitek, LLC	325 Paramount Drive, Raynham MA 02767-0350, United States
19	DePuy Orthopaedics, Inc.	700 Orthopaedic Drive, Warsaw IN 46582, United States
20	DePuy Products, Inc.	700 Orthopaedic Drive, Warsaw IN 46582, United States
21	DePuy Spine, LLC	325 Paramount Drive, Raynham MA 02767-0350, United States
22	DePuy Synthes Institute, LLC	325 Paramount Drive, Raynham MA 02767-0350, United States
23	DePuy Synthes Products, Inc.	325 Paramount Drive, Raynham MA 02767-0350, United States
24	DePuy Synthes Sales, Inc.	325 Paramount Drive, Raynham MA 02767-0350, United States
25	DePuy Synthes, Inc.	700 Orthopaedic Drive, Warsaw IN 46582, United States
26	Ethicon Endo-Surgery, Inc.	4545 Creek Road, Cincinnati OH 45242, United States
27	Ethicon Endo-Surgery, LLC	475 C Street, Suite 200, Guaynabo PR 00969, United States
28	Ethicon LLC	#475 Street C, Suite 401, Los Frailes Industrial Park, Guaynabo PR 00969, United States
29	Ethicon US, LLC	1000 Route 202, Raritan NJ 08869, United States
30	Ethicon, Inc.	1000 Route 202, Raritan NJ 08869, United States
31	Janssen Biotech, Inc.	800/850 Ridgeview Drive, Horsham PA 19044, United States
32	Janssen Global Services, LLC	700 US Route 202 South, Raritan NJ 08869, United States
33	Janssen Oncology, Inc.	10990 Wilshire Blvd. , Suite 440, Los Angeles CA 90024, United States
34	Janssen Ortho LLC	State Road 933 KM 0.1, Mamey Ward, HC 02, Box 19250, Gurabo, 00778, Puerto Rico
35	Janssen Pharmaceuticals, Inc.	1125 Trenton-Harbourton Rd, Titusville NJ 08560, United States
36	Janssen Products, LP	800/850 Ridgeview Drive, Horsham PA 19044, United States
37	Janssen Research & Development, LLC	920 US Route 202, PO Box 300, Raritan NJ 08869, United States
38	Janssen Scientific Affairs, LLC	1125 Trenton-Harbourton Road, Titusville NJ 08560, United States
39	Janssen Supply Group, LLC	200 Tournament Drive, Horsham PA 19044, United States
40	Janssen-Cilag Manufacturing, LLC	State Road 933 KM 0.1, Mamey Ward, HC 02, Box 19250, Gurabo, 00778, Puerto Rico
41	Johnson & Johnson Enterprise Innovation Inc.	One Johnson & Johnson Plaza, New Brunswick NJ 08933, United States
42	Johnson & Johnson Finance Corporation	One Johnson & Johnson Plaza, New Brunswick NJ 08933, United States
43	Johnson & Johnson Health Care Systems Inc.	425 Hoes Lane, Piscataway, NJ, 08855, United States
44	Johnson & Johnson Innovation - JJDC, Inc.	410 George Street, New Brunswick NJ 08933, United States
45	Johnson & Johnson Innovation LLC	410 George Street, New Brunswick NJ 08933, United States
46	Johnson & Johnson Services, Inc.	One Johnson & Johnson Plaza, New Brunswick NJ 08933, United States
47	Johnson & Johnson Surgical Vision, Inc.	31 Technology Drive, Suite 200, Irvine CA 92618, United States
48	Johnson & Johnson Vision Care, Inc.	7500 Centurion Parkway, Jacksonville FL 32256, United States
49	JOM Pharmaceutical Services, Inc.	1 Cottontail Lane, Somerset NJ 08873, United States
50	Laminar, Inc.	1745 Copperhill Blvd, Santa Rosa CA 95403, United States
51	Medical Device Business Services, Inc.	700 Orthopaedic Drive, Warsaw IN 46582, United States
52	Medical Devices & Diagnostics Global Services, LLC	430 Route 22, Bridgewater NJ 08807, United States
53	MegaDyne Medical Products, Inc.	4545 Creek Road, Cincinnati OH 45242, United States
54	Mentor Worldwide LLC	31 Technology Drive, Suite 200, Irvine CA 92618, United States
55	Momenta Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road, Titusville NJ 08560, United States
56	NeuWave Medical, Inc.	3529 Anderson Street, Madison WI 53704, United States
57	NuVera Medical, Inc.	140 Knowles Drive , Los Gatos, CA 95032, United States
58	OMJ Pharmaceuticals, Inc.	1125 Trenton-Harbourton Road, Building K, Titusville NJ 08560, United States
59	Omrix Biopharmaceuticals, Inc.	Route 22 West, Somerville NJ 08876, United States
60	Ortho Biologics LLC	Carr 2, KM 45.6 Campo Alegre, Manati, Puerto Rico, 00674, Puerto Rico
61	Ortho Biotech Holding LLC	7500 Centurion Parkway, Jacksonville FL 32256, United States
62	Patient Service Center LLC	304 Merchant Lane, Pittsburgh, PA 15205, United States
63	Patriot Pharmaceuticals, LLC	200 Tournament Drive, Horsham, PA 19044, United States
64	Percivia LLC	1 Hampshire Street, 5th Floor, Cambridge MA 02139, United States
65	Prosidyan, Inc.	41 Spring Street, Suite 107, New Providence NJ 07974
66	Proteologix, Inc.	1400 Bridge Parkway STE 202, Redwood City, CA 94065, United States
67	Pulsar Vascular, Inc.	47709 Fremont Boulevard, Fremont CA 94538, United States
68	Scios LLC	1125 Trenton Harbourton Road, Titusville NJ 08560, United States
69	Serotiny, Inc.	329 Oyster Point Boulevard, 3rd Floor, South San Francisco CA 94080, United States
70	Shockwave Medical, Inc.	5403 Betsy Ross Drive, Santa Clara CA 95054, United States
71	SterilMed, Inc.	5010 Cheshire Parkway North, Suite 2, Plymouth MN 55446, United States
72	Synthes USA Products, LLC	1302 Wrights Lane East, West Chester PA 19380, United States
73	Synthes USA, LLC	1302 Wrights Lane East, West Chester PA 19380, United States
74	Synthes, Inc.	700 Orthopaedic Drive, Warsaw IN 46582, United States
75	TARIS Biomedical LLC	113 Hartwell Avenue, Lexington MA 02421, United States
76	TearScience, Inc.	510 Cottonwood Drive, Milpitas CA 95035, United States
77	The Anspach Effort, LLC	1302 Wrights Lane East, West Chester PA 19380, United States
78	Tibotec, LLC	1125 Trenton-Harbourton Road, Building K, Titusville NJ 08560, United States
79	Torax Medical, Inc.	4188 Lexington Avenue, Shoreview MN 55126, United States
80	V-Wave Inc.	29219 Canwood St. #100, Agoura Hills, CA 91301, United States
81	Verb Surgical Inc.	5490 Great America Parkway, Santa Clara CA 95054, United States

Attachment B

Surety Bond

Ethicon Endo-Surgery, Inc. is a wholly-owned subsidiary of Johnson & Johnson, a publicly traded company. As such, a surety bond is not required.



NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Ethicon Endo-Surgery, Inc. MDEG License # (if applicable): N/A

Physical Address: 4545 Creek Rd

City: Cincinnati State: OH Zip: 45242

Mailing Address (if different from physical address): 4545 Creek Rd

City: Cincinnati State: OH Zip: 45242

Telephone: 513-337-7000 Website: www.Ethicon.com

Licensing Company Email: ecinibul@its.jnj.com

Section 2: Personal Information

First: Emma Middle: Claire Last: Cinibulk

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

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

Mailing Address: [redacted]

City: [redacted] State: OH Zip: [redacted]

Telephone: [redacted] Email: ecinibul@its.jnj.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		2009 - 2014	
Address	**City**	**State**	**Zip**
4200 Fifth Ave	Pittsburgh	PA	15260
Diploma/Degree obtained, if any	Bachelor of Science in Engineering – Bioengineering		

School Name		From - To (MM/YY – MM/YY)	
Bellbrook High School		2005 - 2009	
Address	**City**	**State**	**Zip**
3737 Upper Bellbrook Rd	Bellbrook	OH	45305
Diploma/Degree obtained, if any	High School		

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

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/18 - Present	[redacted]	[redacted]	OH	[redacted]
From - To (MM/YY – MM/YY) 05/17 - 06/18			State OH	
From - To (MM/YY – MM/YY) 07/15-05/17			State OH	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Ethicon Endo-Surgery, Inc.			04/2025 – Present	
Business Address		City	State	Zip
4545 Creek Rd		Cincinnati	OH	45242
Phone	Title		Number of Employed Hours	
513-337-7000	Principal Quality Engineer		960	

Description of Duties

In addition to responsibilities listed under Staff Quality Systems Engineer role below, also leads activities related to the Franchise Records Management policy and procedures, ensuring alignment with Johnson & Johnson's WW Records Information Management standards and applicable Quality Standards.

Business Name			From - To (MM/YY – MM/YY)	
Ethicon Endo-Surgery, Inc.			01/2023 – 04/2025	
Business Address		City	State	Zip
4545 Creek Rd		Cincinnati	OH	45242
Phone	Title		Number of Employed Hours	
513-337-7000	Staff Quality Systems Engineer		1500+	

Description of Duties

Serving as Quality Systems subject matter expert, tracking and reporting CAPA action plan status/completion as it relates to failure/root cause investigation, and quality systems improvement efforts. Provides guidance to CAPA owners and teams to ensure compliance to procedural requirements as well as ensure sound root cause investigation, corrective action identification, and development of effectiveness monitoring plans.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Emma Cinlar

Original Signature (electronic, copies or stamps not accepted)

11/3/2025

Date

I, Emma Cinibulk, **certify that as the MDEG Administrator for**

Ethicon Endo-Surgery, Inc.,

that I (initial that you have read and meet the following requirements):

1. EC Have a high school diploma or its equivalent;
2. EC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. EC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. EC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Emma Cinibulk
Print Name (First, Last)

Emma Cinibulk
Original Signature (electronic, copies or stamps not accepted)

11/3/2025
Date

Board Use Only	Date Received: 11/17/25

Family/Last Name	Given/First Name	Business Address
Abell	Tammy	1000 US Highway 202 S, Raritan, New Jersey, 08869
ADAIR	MARTIN	1000 US Highway 202 S, Raritan, New Jersey, 08869
Altiveros	Isabella	1000 US Highway 202 S, Raritan, New Jersey, 08869
Atchley	Lauren	1000 US Highway 202 S, Raritan, New Jersey, 08869
Baldisserotto	Mark	1000 US Highway 202 S, Raritan, New Jersey, 08869
BANAS	CATHIE	1000 US Highway 202 S, Raritan, New Jersey, 08869
Broeker	David	1000 US Highway 202 S, Raritan, New Jersey, 08869
Bryant	Vaughan	1000 US Highway 202 S, Raritan, New Jersey, 08869
Carter	Megan	1000 US Highway 202 S, Raritan, New Jersey, 08869
CHEN	GLADYS	1000 US Highway 202 S, Raritan, New Jersey, 08869
Chowdhury	Shahidul	1000 US Highway 202 S, Raritan, New Jersey, 08869
Ciner	Selin	1000 US Highway 202 S, Raritan, New Jersey, 08869
Cummings	Patrick	1000 US Highway 202 S, Raritan, New Jersey, 08869
Cutrone	Vincent	1000 US Highway 202 S, Raritan, New Jersey, 08869
DeBalso	Jason	1000 US Highway 202 S, Raritan, New Jersey, 08869
Ellis	Christina	1000 US Highway 202 S, Raritan, New Jersey, 08869
Fassak	Ryan	1000 US Highway 202 S, Raritan, New Jersey, 08869
Fedor	Elana	1000 US Highway 202 S, Raritan, New Jersey, 08869
Flaherty	Colin	1000 US Highway 202 S, Raritan, New Jersey, 08869
Flick	Cristie	1000 US Highway 202 S, Raritan, New Jersey, 08869
Flynn	Mark	1000 US Highway 202 S, Raritan, New Jersey, 08869
Garcia	Andy	1000 US Highway 202 S, Raritan, New Jersey, 08869
Granger	Jack	1000 US Highway 202 S, Raritan, New Jersey, 08869
Gulick	Snapper	1000 US Highway 202 S, Raritan, New Jersey, 08869
GUZMAN	CLAUDIA	1000 US Highway 202 S, Raritan, New Jersey, 08869
Hanley	Ella	1000 US Highway 202 S, Raritan, New Jersey, 08869
Harris	Maya	1000 US Highway 202 S, Raritan, New Jersey, 08869
Hathaway	Lauren	1000 US Highway 202 S, Raritan, New Jersey, 08869
Holland	John	1000 US Highway 202 S, Raritan, New Jersey, 08869
Hrizuk	Jonathan	1000 US Highway 202 S, Raritan, New Jersey, 08869
HURLEY	ERIC	1000 US Highway 202 S, Raritan, New Jersey, 08869
Jones	Nathaniel	1000 US Highway 202 S, Raritan, New Jersey, 08869
Khalil	Suzy	1000 US Highway 202 S, Raritan, New Jersey, 08869
King	Myles	1000 US Highway 202 S, Raritan, New Jersey, 08869
Kissling	Leah	1000 US Highway 202 S, Raritan, New Jersey, 08869
KLEMCHALK	STEVEN	1000 US Highway 202 S, Raritan, New Jersey, 08869
Kratz	Megan	1000 US Highway 202 S, Raritan, New Jersey, 08869
LANE	ERIKA	1000 US Highway 202 S, Raritan, New Jersey, 08869
Lanza	Joseph	1000 US Highway 202 S, Raritan, New Jersey, 08869
Lau	Lewis	1000 US Highway 202 S, Raritan, New Jersey, 08869
Leung	Calvin	1000 US Highway 202 S, Raritan, New Jersey, 08869
LI	ANGELA	1000 US Highway 202 S, Raritan, New Jersey, 08869
LIM	OLIVER	1000 US Highway 202 S, Raritan, New Jersey, 08869

Magrini	Glenn	1000 US Highway 202 S, Raritan, New Jersey, 08869
Maiorelli	Adrienne	1000 US Highway 202 S, Raritan, New Jersey, 08869
McPhaden	Tracy	1000 US Highway 202 S, Raritan, New Jersey, 08869
Melendez	Laura	1000 US Highway 202 S, Raritan, New Jersey, 08869
MERKLINGER	RICHARD	1000 US Highway 202 S, Raritan, New Jersey, 08869
Muniz	Zenaida	1000 US Highway 202 S, Raritan, New Jersey, 08869
MURPHY	TINA	1000 US Highway 202 S, Raritan, New Jersey, 08869
ORAVSKY	SHANE	1000 US Highway 202 S, Raritan, New Jersey, 08869
ORTEGA	JOANA	1000 US Highway 202 S, Raritan, New Jersey, 08869
PALAGRUTO	ANTHONY	1000 US Highway 202 S, Raritan, New Jersey, 08869
Parameswaran	Chitra	1000 US Highway 202 S, Raritan, New Jersey, 08869
Pena	Ramon	1000 US Highway 202 S, Raritan, New Jersey, 08869
PEREZ CERQUEDA	JENIFER	1000 US Highway 202 S, Raritan, New Jersey, 08869
Petrone Toth	Patricia	1000 US Highway 202 S, Raritan, New Jersey, 08869
Presser	Victoria	1000 US Highway 202 S, Raritan, New Jersey, 08869
Priece	Emily	1000 US Highway 202 S, Raritan, New Jersey, 08869
Reddy	STACEY	1000 US Highway 202 S, Raritan, New Jersey, 08869
RIZKALLAH	MONICA	1000 US Highway 202 S, Raritan, New Jersey, 08869
ROBERTS	JASON	1000 US Highway 202 S, Raritan, New Jersey, 08869
RUSSO	JOHN	1000 US Highway 202 S, Raritan, New Jersey, 08869
Russo	Anthony	1000 US Highway 202 S, Raritan, New Jersey, 08869
SPURGEON	JENNIFER	1000 US Highway 202 S, Raritan, New Jersey, 08869
Summers	Cassandra	1000 US Highway 202 S, Raritan, New Jersey, 08869
Svoboda	Jacob	1000 US Highway 202 S, Raritan, New Jersey, 08869
Talluto	Enza	1000 US Highway 202 S, Raritan, New Jersey, 08869
TEASDALE	CHRISTOPHER	1000 US Highway 202 S, Raritan, New Jersey, 08869
Thosar	Prachi	1000 US Highway 202 S, Raritan, New Jersey, 08869
TORRES	ELISA	1000 US Highway 202 S, Raritan, New Jersey, 08869
Tripp	Andrea	1000 US Highway 202 S, Raritan, New Jersey, 08869
Uthgenannt	Samuel	1000 US Highway 202 S, Raritan, New Jersey, 08869
Vassar	Tajon	1000 US Highway 202 S, Raritan, New Jersey, 08869
Vidolin	Lucas	1000 US Highway 202 S, Raritan, New Jersey, 08869

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023
or

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the transition period from to

Commission file number 1-3215

Johnson & Johnson

(Exact name of registrant as specified in its charter)

New Jersey	22-1024240
(State of incorporation)	(I.R.S. Employer Identification No.)
One Johnson & Johnson Plaza New Brunswick, New Jersey	08933
(Address of principal executive offices)	(Zip Code)

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)
Registrant's telephone number, including area code: (732) 524-0400

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol(s)
Common Stock, Par Value $1.00	JNJ
0.650% Notes Due May 2024	JNJ24C
5.50% Notes Due November 2024	JNJ24BP
1.150% Notes Due November 2028	JNJ28
1.650% Notes Due May 2035	JNJ35

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑
The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $430 billion.
On February 6, 2024, there were 2,408,787,228 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of the registrant's proxy statement for its 2024 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

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Cautionary note regarding forward-looking statements

This Annual Report on Form 10-K and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the Company) also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates" and other words of similar meaning in conjunction with, among other things: discussions of future operations; expected operating results and financial performance; impact of planned acquisitions and dispositions; impact and timing of restructuring initiatives, including associated cost savings and other benefits; the Company's strategy for growth; product development activities; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks related to product development, market success and competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing generic, biosimilar or other products and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks related to product liability, litigation and regulatory activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (U.S. FDA) (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- The impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- The impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the healthcare industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products, licensing and patent rights; sales and promotion of healthcare products; access to, and reimbursement and pricing for, healthcare products and services; environmental protection; and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets, including requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- The issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks related to the Company's strategic initiatives, healthcare market trends and the realization of benefits from the separation of the Company's Consumer Health Business

- Pricing pressures resulting from trends toward healthcare cost containment, including the continued consolidation among healthcare providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payors of healthcare expenses, significant new entrants to the healthcare markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of healthcare products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected;
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected;
- The Company's ability to divest the Company's remaining ownership interest in Kenvue Inc. (Kenvue) and realize the anticipated benefits from the separation; and
- Kenvue's ability to succeed as a standalone publicly traded company.

Risks related to economic conditions, financial markets and operating internationally

- The risks associated with global operations of the Company and its customers and suppliers, including foreign governments in countries in which the Company operates;
- The impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- The impact of global public health crises and pandemics;

- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations;
- The impact of global or economic changes or events, including global tensions and war; and
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world, including social and economic disruptions and instability of financial and other markets.

Risks related to supply chain and operations

- Difficulties and delays in manufacturing, internally, through third-party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors, which could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities.

Investors also should carefully read the risk factors described in Item 1A of this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and in Item 1A to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

Part I

Item 1. Business

General

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. Johnson & Johnson is a holding company, with operating companies conducting business in virtually all countries of the world. The Company's primary focus is products related to human health and well-being. Johnson & Johnson was incorporated in the State of New Jersey in 1887.

The Executive Committee of Johnson & Johnson is the principal management group responsible for the strategic operations and allocation of the resources of the Company. This Committee oversees and coordinates the activities of the Company's two business segments, Innovative Medicine (previously referred to as Pharmaceutical) and MedTech. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies. Each subsidiary within the business segments is, with limited exceptions, managed by residents of the country where located.

Segments of business

Following the completion of the separation of the Consumer Health business (Kenvue) in August 2023, the Company is now organized into two business segments: Innovative Medicine and MedTech. Additional information required by this item is incorporated herein by reference to the narrative and tabular descriptions of segments and operating results under Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition of this Report, and Note 17 Segments of business and geographic areas of the notes to consolidated financial statements included in Item 8 of this Report.

Innovative Medicine

The Innovative Medicine segment is focused on the following therapeutic areas: Immunology (e.g., rheumatoid arthritis, psoriatic arthritis, inflammatory bowel disease and psoriasis); Infectious Diseases (e.g., HIV/AIDS); Neuroscience (e.g., mood disorders, neurodegenerative disorders and schizophrenia); Oncology (e.g., prostate cancer, hematologic malignancies, lung cancer and bladder cancer); Cardiovascular and Metabolism (e.g., thrombosis, diabetes and macular degeneration) and Pulmonary Hypertension (e.g., Pulmonary Arterial Hypertension). Medicines in this segment are distributed directly to retailers, wholesalers, distributors, hospitals and healthcare professionals for prescription use. Key products in the Innovative Medicine segment include: REMICADE (infliximab), a treatment for a number of immune-mediated inflammatory diseases; SIMPONI (golimumab), a subcutaneous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis and moderately active to severely active ulcerative colitis; SIMPONI ARIA (golimumab), an intravenous treatment for adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis and active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older; STELARA (ustekinumab), a treatment for adults and children with moderate to severe plaque psoriasis, for adults with active psoriatic arthritis, for adults with moderately to severely active Crohn's disease and treatment of moderately to severely active ulcerative colitis; TREMFYA (guselkumab), a treatment for adults with moderate to severe plaque psoriasis and active psoriatic arthritis; EDURANT (rilpivirine), PREZISTA (darunavir) and PREZCOBIX/REZOLSTA (darunavir/cobicistat), antiretroviral medicines for the treatment of human immunodeficiency virus (HIV) in combination with other antiretroviral products and SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), a once-daily single tablet regimen for the treatment of HIV; CONCERTA (methylphenidate HCl) extended-release tablets CII, a treatment for attention deficit hyperactivity disorder; INVEGA SUSTENNA/XEPLION (paliperidone palmitate), for the treatment of schizophrenia and schizoaffective disorder in adults; INVEGA TRINZA/TREVICTA (paliperidone palmitate), for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA for at least four months; SPRAVATO (Esketamine), a nasal spray, used along with an oral antidepressant, to treat adults with treatment-resistant depression (TRD) and depressive symptoms in adults with major depressive disorder (MDD) with suicidal thoughts or actions; CARVYKTI (ciltacabtagene autoleucel), a chimeric antigen receptor (CAR)-T-cell therapy for the treatment of patients with relapsed/refractory multiple myeloma; ZYTIGA (abiraterone

acetate), a treatment for patients with prostate cancer; ERLEADA (apalutamide), a next-generation androgen receptor inhibitor for the treatment of patients with prostate cancer; IMBRUVICA (ibrutinib), a treatment for certain B-cell malignancies, or blood cancers and chronic graft versus host disease; DARZALEX (daratumumab), a treatment for multiple myeloma; DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), a treatment for multiple myeloma and light chain (AL) Amyloidosis; XARELTO (rivaroxaban), an oral anticoagulant for the prevention of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery; to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; and for the treatment and reduction of risk of recurrence of DVT and PE to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) and peripheral artery disease (PAD); for the treatment and secondary prevention of thromboembolism in pediatric patients; and for thromboprophylaxis in pediatric patients following the Fontan procedure; OPSUMIT (macitentan) as monotherapy or in combination, indicated for the long-term treatment of pulmonary arterial hypertension (PAH); UPTRAVI (selexipag), the only approved oral and intravenous selective IP receptor agonist targeting a prostacyclin pathway in PAH. Many of these medicines were developed in collaboration with strategic partners or are licensed from other companies and maintain active lifecycle development programs.

MedTech

The MedTech segment includes a broad portfolio of products used in the Interventional Solutions, Orthopaedics, Surgery and Vision categories. Interventional Solutions include electrophysiology products (Biosense Webster) to treat heart rhythm disorders, the heart recovery portfolio (Abiomed) which includes technologies to treat severe coronary artery disease requiring high-risk PCI or AMI cardiogenic shock, and Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke. The Orthopaedics portfolio (DePuy Synthes) includes products and enabling technologies that support Hips, Knees, Trauma, and Spine, Sports & Other. The Surgery portfolios include advanced and general surgery technologies (Ethicon), as well as solutions that focus on breast aesthetics (Mentor), and Ear, Nose and Throat (Acclarent) procedures. Johnson & Johnson Vision products include ACUVUE Brand contact lenses and TECNIS intraocular lenses for cataract surgery. These products are distributed to wholesalers, hospitals and retailers, and used predominantly in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

Geographic areas

Johnson & Johnson and its subsidiaries (the Company) have approximately 131,900 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the healthcare field. The Company conducts business in virtually all countries of the world with the primary focus on products related to human health and well-being.

The products made and sold in the international business include many of those described above under Segments of Business – Innovative Medicine and MedTech. However, the principal markets, products and methods of distribution in the international business vary with the country and the culture. The products sold in international business include those developed in the U.S. and by subsidiaries abroad.

Investments and activities in some countries outside the U.S. are subject to higher risks than comparable U.S. activities because the investment and commercial climate may be influenced by financial instability in international economies, restrictive economic policies and political and legal system uncertainties.

Raw materials

Raw materials essential to the Company's business are generally readily available from multiple sources. Where there are exceptions, the temporary unavailability of those raw materials would not likely have a material adverse effect on the financial results of the Company.

Patents

The Company's subsidiaries have made a practice of obtaining patent protection on their products and processes where possible. They own, or are licensed under, a significant number of patents in the U.S. and other countries relating to their products, product uses, formulations and manufacturing processes, which in the aggregate are believed to be of material importance to the Company in the operation of its businesses. The Company's subsidiaries face patent challenges from third parties, including challenges seeking to manufacture and market generic and biosimilar versions of the Company's key

pharmaceutical products prior to expiration of the applicable patents covering those products. Significant legal proceedings and claims involving the Company's patent and other intellectual property are described in Note 19 Legal proceedings—Intellectual property of the Notes to Consolidated Financial Statements included in Item 8 of this Report.

Sales of the Company's largest product, STELARA (ustekinumab) accounted for approximately 12.8% of the Company's total revenues for fiscal 2023. Accordingly, the patents related to this product are believed to be material to the Company. Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, owns patents specifically related to STELARA. The latest expiring United States composition of matter patent expired in 2023. As a result of settlements and other agreements with third parties, the Company does not anticipate the launch of a biosimilar version of STELARA before January 1, 2025 in the United States. The latest expiring European composition of matter patent (Supplementary Protection Certificate) expires in 2024.

Sales of the Company's second largest product, collectively DARZALEX (daratumumab) and DARZALEX FASPRO (daratumumab and hyaluronidase-fihj), accounted for approximately 11.4% of the Company's total revenues for fiscal 2023. Accordingly, the patents related to this product are believed to be material to the Company. Genmab A/S owns two patent families related to DARZALEX, and Janssen Biotech, Inc. has an exclusive license to those patent families. The two patent families both expire in the United States in 2029, and in Europe, compound patent protection in select countries extends to 2031/2032. Janssen Biotech, Inc. owns a separate patent portfolio related to DARZALEX FASPRO.

Trademarks

The Company's subsidiaries have made a practice of selling their products under trademarks and of obtaining protection for these trademarks by all available means. These trademarks are protected by registration in the U.S. and other countries where such products are marketed. The Company considers these trademarks in the aggregate to be of material importance in the operation of its businesses.

Seasonality

Worldwide sales do not reflect any significant degree of seasonality; however, spending has typically been heavier in the fourth quarter of each year than in other quarters. This reflects increased spending decisions, principally for research and development activity.

Competition

In all of their product lines, the Company's subsidiaries compete with companies both locally and globally. Competition exists in all product lines without regard to the number and size of the competing companies involved. Competition in research, both internally and externally sourced, involving the development and the improvement of new and existing products and processes, is particularly significant. The development of new and innovative products, as well as protecting the underlying intellectual property of the Company's product portfolio, is important to the Company's success in all areas of its business. The competitive environment requires substantial investments in continuing research.

Environment

The Company is subject to a variety of environmental laws and regulations in the United States and other jurisdictions. The Company believes that its operations comply in all material respects with applicable environmental laws and regulations. The Company's compliance with these requirements is not expected to have a material effect upon its capital expenditures, cash flows, earnings or competitive position.

Regulation

The Company's businesses are subject to varying degrees of governmental regulation in the countries in which operations are conducted, and the general trend is toward increasingly stringent regulation and enforcement. The Company is subject to costly and complex U.S. and foreign laws and governmental regulations and any adverse regulatory action may materially adversely affect the Company's financial condition and business operations. In the U.S., the pharmaceutical product and medical technology industries have long been subject to regulation by various federal and state agencies, primarily as to product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory powers by the U.S. Food and Drug Administration (the U.S. FDA) continues to result in increases in the amounts of testing and documentation required for U.S. FDA approval of new drugs and devices and a corresponding increase in the expense of product introduction. Similar trends are also evident in major markets outside of the U.S.

The new medical device regulatory framework and the evolving privacy, data localization, and emerging cyber security laws and regulations around the world are examples of such increased regulation. Within the U.S., an increasing number of U.S. States have enacted comprehensive privacy laws and federal regulators (e.g., the U.S. FDA, FTC and HHS) continue to stress the intersection of health and privacy as a compliance and enforcement priority. In the EU, multiple directives and laws (including NIS2, EHDS, the Data Act, the Cyber Resilience Act, and the AI Act) are rapidly changing privacy and cybersecurity compliance requirements while introducing new enforcement risks. In addition, China has introduced broad personal information protection and data security regulations, with more anticipated, thereby increasing China's scrutiny of company compliance and data transfer practices. With other jurisdictions enacting similar privacy laws, local data protection authorities will force greater accountability on the collection, access and use of personal data in the healthcare industry. These laws can also restrict transfers of data across borders, potentially impacting how data-driven health care solutions are developed and deployed globally in a compliant manner. Moreover, as a result of the broad scale release and availability of Artificial Intelligence (AI) technologies such as generative AI, a global trend towards more comprehensive and nuanced regulation (e.g., White House's Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence; the EU AI Act) to ensure the ethical use, privacy, and security of AI is underway that includes standards for transparency, accountability, and fairness, which will require compliance developments or enhancements.

The regulatory agencies under whose purview the Company operates have administrative powers that may subject it to actions such as product withdrawals, recalls, seizure of products and other civil and criminal sanctions. In some cases, the Company's subsidiaries may deem it advisable to initiate product recalls regardless of whether it has been required or directed to.

The U.S. FDA and regulatory agencies around the globe are also increasing their enforcement activities. If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our pharmaceutical products or medical technologies are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such products, detain or seize adulterated or misbranded products, order a recall, repair, replacement, or refund of such products, refuse to grant pending applications for marketing authorization or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the products present unreasonable risks of substantial harm to the public health. The U.S. FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The U.S. FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future clearances or approvals, and could result in a substantial modification to our business practices and operations. Equivalent enforcement mechanisms exist in different countries in which we conduct business.

The costs of human healthcare have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the U.S., attention has been focused by states, regulatory agencies and Congress on prices, profits, overutilization and the quality and costs of healthcare generally. Laws and regulations have been enacted to require adherence to strict compliance standards and prevent fraud and abuse in the healthcare industry. There is increased focus on interactions and financial relationships between healthcare companies and healthcare providers. Various state and federal transparency laws and regulations require disclosures of payments and other transfers of value made to certain healthcare practitioners, including physicians, teaching hospitals, and certain non-physician practitioners. Federal and foreign laws governing international business practices require strict compliance with anti-bribery standards and certain prohibitions with respect to payments to any foreign government official. Payors and Pharmacy Benefit Managers (PBMs) are a potent force in the marketplace, and increased attention is being paid to the impact of PBM practices on healthcare cost and access in the U.S.

Our business has been and continues to be affected by federal and state legislation that alters the pricing, coverage, and reimbursement landscape. At the federal level, in August 2022, President Biden signed into law the Inflation Reduction Act

(IRA), which includes provisions that effectively authorize the government to establish prices for certain high-spend single-source drugs and biologics reimbursed by the Medicare program, starting in 2026 for Medicare Part D drugs and 2028 for Medicare Part B drugs. On August 29, 2023, the Centers for Medicare & Medicaid Services ("CMS") published the first "Selected Drug" list, which includes XARELTO and STELARA as well as IMBRUVICA, which is developed in collaboration and co-commercialized in the U.S. with Pharmacyclics LLC, an AbbVie company. The Selected Drug list also included other medicines targeting disease states that are prevalent in the Medicare population. There remains uncertainty, however, regarding how the federal government will establish prices for the selected products, as the IRA specifies a ceiling price but not a minimum price. In any event, we anticipate that the selected products will be subjected to a government-established price for the Medicare population.

The IRA also contains provisions that impose rebates if certain prices increase at a rate that outpaces the rate of inflation, beginning October 1, 2022, for Medicare Part D drugs and January 1, 2023, for Medicare Part B drugs. Separate IRA provisions redesign the Medicare Part D benefit in various ways, including by shifting a greater portion of costs to manufacturers within certain coverage phases and replacing the Part D coverage gap discount program with a new manufacturer discounting program. Failure to comply with IRA provisions may subject manufacturers to various penalties, including civil monetary penalties.

In July 2023, Janssen Pharmaceuticals, Inc. (Janssen) filed litigation against the U.S. Department of Health and Human Services as well as the Centers for Medicare and Medicaid Services challenging the constitutionality of the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program. The litigation requests a declaration that the IRA violates Janssen's rights under the First Amendment and the Fifth Amendment to the Constitution and therefore that Janssen is not subject to the IRA's mandatory pricing scheme. The impact of the IRA on our business and the broader pharmaceutical industry remains uncertain, as litigation filed by Janssen and other pharmaceutical companies remains ongoing and CMS has yet to publicly announce the maximum fair price for each of the selected drugs.

Additionally, we expect continued scrutiny on drug pricing and government price reporting from Congress, agencies, and other bodies at the federal and state levels, which may result in additional regulations or other mechanisms to increase pricing transparency and controls.

There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing, including in the Medicare and Medicaid programs. This changing legal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal and state law, and potential modification or repeal of these laws, will ultimately affect the industry. The IRA and any other federal or state legislative change could affect the pricing and market conditions for our products.

In addition, business practices in the healthcare industry have come under increased scrutiny, particularly in the U.S., by government agencies and state attorneys general, and resulting investigations and prosecutions carry the risk of significant civil and criminal penalties. Of note is the increased enforcement activity by data protection authorities in various jurisdictions, particularly in the European Union, where significant fines have been levied on companies for data breaches, violations of privacy requirements, and unlawful cross-border data transfers. In the U.S., the Federal Trade Commission has stepped up enforcement of data privacy with several significant settlements (including settlements concerning the downstream sharing of personal information and use and disclosure of personal health data) and there have been a material increase in class-action lawsuits linked to the collection and use of biometric data and use of tracking technologies.

Further, the Company relies on global supply chains, and production and distribution processes, that are complex, and subject to increasing regulatory requirements that may affect sourcing, supply and pricing of materials used in the Company's products. These processes also are subject to complex and lengthy regulatory approvals.

Employees and human capital management

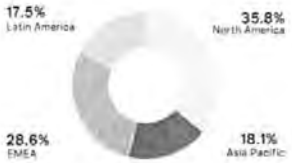
As of December 31, 2023, the number of employees was approximately:

Employees[1]
Full-time equivalent (FTE) positions[2]

[1] "Employee" is defined as an individual working full-time or part-time, excluding fixed term employees, interns and co-op employees. Employee data may not include full population from more recently acquired companies and individuals on long-term disability are excluded. Contingent workers, contractors and subcontractors are also excluded.

[2] FTE represents the total number of full-time equivalent positions and does not reflect the total number of individual employees as some work part time.

Employees by region (in percentages)



Strategy

The Company believes that its employees are critical to its continued success and are an essential element of its long-term strategy. Management is responsible for ensuring that its policies and processes reflect and reinforce the Company's desired corporate culture, including policies and processes related to strategy, risk management, and ethics and compliance. The Company's human capital management strategy is built on three fundamental focus areas:

- Attracting and recruiting the best talent
- Developing and retaining talent
- Empowering and inspiring talent

Underpinning these focus areas are ongoing efforts to cultivate and foster a culture built on diversity, equity and inclusion (DEI), innovation, health, well-being and safety, where the Company's employees are encouraged to succeed both professionally and personally while helping the Company achieve its business goals.

Culture and employee engagement

At the Company, employees are guided by Our Credo which sets forth the Company's responsibilities to patients, consumers, customers, healthcare professionals, employees, communities and shareholders. Employees worldwide must adhere to the Company's Code of Business Conduct which sets basic requirements and serves as a foundation for the Company policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors in every market where it operates. The Company conducts global surveys that offer its employees the ability to provide feedback and valuable insight to help address potential human resources risks and identify opportunities to improve. In 2023, 94% of global employees across 76 countries participated in Our Credo Survey which was offered in 36 languages.

Growth and development

To lead in the changing healthcare landscape, it is crucial that the Company continue to attract and retain top talent. In 2023, the Company's voluntary turnover rate was 7%. The Company believes that its employees must be equipped with the right knowledge and skills and be provided with opportunities to grow and develop in their careers. Accordingly, professional development programs and educational resources are available to all employees. The Company's objective is to foster a learning culture that helps shape each person's unique career path while creating a robust pipeline of talent to deliver on the Company's long-term strategies. In furtherance of this objective, the Company deploys a global approach to ensure development is for everyone, regardless of where they are on their career journey. To prioritize learning, the Company recently held Johnson & Johnson's first Global Learning Day. Employees were encouraged to set aside a full day to explore skill-building courses across five areas: leadership, business skills, digital upskilling, DEI, and well-being, on J&J Learn, the Company's new learning platform.

Diversity, equity, and inclusion (DEI)

The Company is committed to workplace diversity and to cultivating, fostering, and advancing a culture of equity and inclusion. The Company's evidenced-based global enterprise Diversity, Equity and Inclusion strategy recognizes how DEI accelerates the Company's ability to meet the changing needs of the communities the Company serves in, as outlined in Our Credo. The Company's DEI Vision is: *Be yourself, change the world*. The Company's DEI Mission is: *Make diversity, equity and inclusion how we work everyday*. The Company's enterprise DEI Strategy is aligned to the DEI Vision and Mission and rests on four core pillars:

- Build a workforce of individuals with diverse backgrounds, cultures, abilities and perspectives
- Foster a culture of inclusion where every individual belongs
- Transform talent and business processes to achieve equitable opportunities for all
- Drive innovation and growth with our business to serve diverse markets around the world

The Company's DEI strategy is guided by internal and external insights, global best practices and continual employee feedback and recognizes that while diversity changes by location, inclusion is the same everywhere.

Compensation and benefits

As part of the Company's total rewards philosophy, the Company offers competitive compensation and benefits to attract and retain top talent. The Company is committed to fairness and equitable treatment in its compensation and benefits for employees at all levels. The Company observes legal minimum wage provisions and exceeds them where possible. The Company's total rewards offerings include an array of programs to support its employees' well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off, leave programs, flexible work schedules and employee assistance programs. In recognition of the Company's commitment to help employees balance their personal and professional responsibilities, the Company enhanced its caregiver, bereavement, and volunteer paid leave benefits, effective July 2023.

Health, wellness and safety

The Company's investment in employee health, well-being and safety is built on its conviction that advancing health for humanity starts with advancing the health of its employees. With the right awareness, focus, practices and tools, the Company ensures that all its employees around the world, as well as temporary contractors and visitors to the Company's sites, can work safely. The Company has continuously expanded health and well-being programs throughout the Company and across the globe, incorporating new thinking and technologies to keep its offerings best-in-class and to help employees achieve their personal health goals. The programs and practices the Company advances for total health—physical, mental, emotional and financial—ensure employee health protection for emerging health risks. The Company continues to address our employees needs through J&J Flex, a hybrid model that empowers the Company's office-based employees to find the right productivity and balance of in-person and remote work.

Available information

The Company's main corporate website address is www.jnj.com. The Company makes its SEC filings available on the Company's website at www.investor.jnj.com/financial-publications/sec-filings, as soon as reasonably practicable after having been electronically filed or furnished to the SEC. The Company's SEC filings are also available at the SEC's website at www.sec.gov.

Investors and the public should note that the Company also announces information at www.factsaboutourpreeclampsiaclaims.com, www.factsaboutlaic.com and www.LLTManagementInformation.com. We use these websites to communicate with investors and the public about our products, litigation and other matters. It is possible that the information we post to these websites could be deemed to be material information. Therefore, we encourage investors and others interested in the Company to review the information posted to these websites in conjunction with www.jnj.com, the Company's SEC filings, press releases, public conference calls and webcasts.

In addition, the Amended and Restated Certificate of Incorporation, By-Laws, the written charters of the Audit Committee, the Compensation & Benefits Committee, the Nominating & Corporate Governance Committee, the Regulatory Compliance & Sustainability Committee, the Science & Technology Committee and any special committee of the Board of Directors and the Company's Principles of Corporate Governance, Code of Business Conduct (for employees), Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, and other corporate governance materials, are available at www.investor.jnj.com/governance/corporate-governance-overview on the Company's website and will be provided without charge to any shareholder submitting a written request, as provided above. The information on www.jnj.com, www.factsaboutourpreeclampsiaclaims.com, www.factsaboutlaic.com and www.LLTManagementInformation.com is not, and will not be deemed, a part of this Report or incorporated into any other filings the Company makes with the SEC.

Item 1A. Risk factors

An investment in the Company's common stock or debt securities involves risks and uncertainties. The Company seeks to identify, manage and mitigate risks to our business, but uncertainties and risks are difficult to predict and many are outside of the Company's control and cannot therefore be eliminated. In addition to the other information in this report and the Company's other filings with the SEC, investors should consider carefully the factors set forth below. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. If known or unknown risks or uncertainties materialize, the Company's business, results of operations or financial condition could be adversely affected, potentially in a material way.

Risks related to our business, industry and operations

The Company's businesses operate in highly competitive product markets and competitive pressures could adversely affect the Company's earnings.

The Company faces substantial competition in its two operating segments and in all geographic markets. The Company's businesses compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, intellectual property rights, product performance, real or perceived product advantages, pricing and availability and rate of reimbursement. The Company also competes with other market participants in securing rights to acquisitions, collaborations and licensing agreements with third parties. Competition for rights to product candidates and technologies may result in significant investment and acquisition costs and onerous agreement terms for the Company. Competitors' development of more effective or less costly products, and/or their ability to secure patent and other intellectual property rights and successfully market products ahead of the Company, could negatively impact sales of the Company's existing products as well as its ability to bring new products to market despite significant prior investment in the related product development. The Company may also experience operational and financial risk in connection with acquisitions if we are unable to fully identify potential risks and liabilities associated with acquired businesses or products, successfully integrate operations and employees, and successfully identify and realize synergies with existing businesses while containing acquisition-related strain on our management, operations and financial resources.

For the Company's Innovative Medicine businesses, loss of patent exclusivity for a product often is followed by a substantial reduction in sales as competitors gain regulatory approval for generic and other competing products and enter the market. Similar competition can be triggered by the loss of exclusivity for a biological product. For the Company's MedTech businesses, technological innovation, product quality, reputation and customer service are especially important to competitiveness. Development by other companies of new or improved products, processes and technologies could threaten to make the Company's products or technologies less desirable, less economical or obsolete. The Company's business and operations will be negatively impacted if we are unable to introduce new products or technological advances that are safe, more effective, more effectively marketed or otherwise outperform those of our competitors.

Interruptions and delays in manufacturing operations could adversely affect the Company's business, sales and reputation.

The Company's manufacturing of products requires the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company's subsidiaries operate 61 manufacturing facilities as well as sourcing from thousands of suppliers around the world. The Company has in the past, and may in the future, face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, labor shortages, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest, terrorist attacks and epidemics or pandemics. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

The Company relies on third parties to manufacture and supply certain of our products. Any failure by or loss of a third-party manufacturer or supplier could result in delays and increased costs, which may adversely affect our business.

The Company relies on third parties to manufacture and supply certain of our raw materials, component parts and products. We depend on these third-party manufacturers to allocate to us a portion of their manufacturing capacity sufficient to meet our needs, to produce products of acceptable quality and at acceptable manufacturing yields and to deliver those products to us on a timely basis and at acceptable prices. However, we cannot guarantee that these third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements, which could result in lost sales and have an adverse effect on our business.

Other risks associated with our reliance on third parties to manufacture these products include reliance on the third party for regulatory compliance and quality assurance, misappropriation of the Company's intellectual property, limited ability to manage our inventory, possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the manufacturing agreement by the third party at a time that is costly or inconvenient for us. Moreover, if any of our third-party manufacturers suffers any damage to facilities, loses benefits under material agreements, experiences power outages, encounters financial difficulties, is unable to secure necessary raw materials from its suppliers or suffers any other reduction in efficiency, the Company may experience significant business disruption. In the event of any such disruption, the Company would need to seek and source other qualified third-party manufacturers, likely resulting in further delays and increased costs which could affect our business adversely.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the internet. Third parties may illegally distribute and sell counterfeit versions of our products, which do not meet our rigorous manufacturing and testing standards. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured – often in unregulated, unlicensed, uninspected and unsanitary sites – as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

Global health crises, pandemics, epidemics, or other outbreaks could adversely disrupt or impact certain aspects of the Company's business, results of operations and financial condition.

We are subject to risks associated with global health crises, epidemics, pandemics and other outbreaks (such incident(s), a health crisis or health crises). For example, the COVID-19 pandemic adversely impacted certain aspects of the Company's business, results of operations and financial condition, including lower sales and reduced customer demand and usage of certain of our products. The spread of any health crises may cause the Company to modify its business practices, and take further actions as may be required by government authorities or as the Company determines are in the best interests of our patients, customers, employees and business partners under such circumstances. While the Company has robust business continuity plans in place across our global supply chain network designed to help mitigate the impact of health crises, these efforts may not completely prevent our business from being adversely affected in the event of a health crisis. Health crises could adversely impact the Company's operations, including, among other things, our manufacturing operations, supply chain, third-party suppliers, sales and marketing, and clinical trial operations. Any of these factors could adversely affect the Company's business, financial results, and global economic conditions generally.

Risks related to government regulation and legal proceedings

Global sales in the Company's Innovative Medicine and MedTech segments may be negatively impacted by healthcare reforms and increasing pricing pressures.

Sales of the Company's Innovative Medicine and MedTech products are significantly affected by reimbursements by third-party payors such as government healthcare programs, private insurance plans and managed care organizations. As part of various efforts to contain healthcare costs, these payors are putting downward pressure on prices at which products will be reimbursed. In the U.S., increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, in part due to continued consolidation among healthcare providers, could result in further pricing pressures. In addition, recent legislation and ongoing political scrutiny on pricing, coverage and reimbursement could result in additional pricing pressures. Specifically, the Inflation Reduction Act of 2022 (IRA) may subject certain products to government-established pricing, potentially impose rebates, and subject manufacturers who fail to adhere to the government's interpretations of the law to penalties. Further, increased third-party utilization of the 340B Federal Drug Discount Program from expanded interpretations of the statute may have a negative impact on the Company's financial performance. Outside the U.S., numerous major markets, including the EU, United Kingdom, Japan and China, have pervasive government involvement in funding healthcare and, in that regard, directly or indirectly impose price controls, limit access to, or reimbursement for, the Company's products, or reduce the value of its intellectual property protection.

4L

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☐ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03711	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stryker Spine, LLC

Physical Address: 2 Pearl Court

City: Allendale State: NJ Zip: 07401

Mailing Address (if different from physical address): Same as physical address.

City: _____ State: _____ Zip: _____

Telephone: (201) 825-4900 Website: _____

Name of Designated Representative (DR): Christopher John Tortora

Licensing Company Email: _____ DR Email: chris.tortora@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
See attached.	9/3/2024	KS	See attached.	See attached.
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
24-255		Kansas Board of Pharmacy		
Reason/Charge				
See attached.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
See attached.			N/A	
Name of Business/Industry/Entity				
See attached.				

Provide explanation below:

See attached.

Original Signature (electronic, copies or stamps not accepted)

3.17.25
Date

Stryker Spine – Nevada Utah Change of Ownership Application

Section 2 - History of Company

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?

Response: Yes, please see the attached agreement entered into with the Kansas Board of Pharmacy. A fine was paid in the amount of $25,000.

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

September 3, 2024

Howmedica Osteonics Corporation
dba Stryker Spine
2 Pearl Ct
Allendale NJ 07401

RE: Case No. 24-255

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $25,000. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

cc:
see next page

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

cc:

Stryker Corporation
6300 S Sprinkle Rd
Portage MI 49002

Stryker Corporation
1941 Stryker Way
Portage MI 49002

Stryker Corporation
5900 Optical Ct
San Jose CA 95138

Stryker Corporation
Stryker Communications, Inc.
571 Silveron Blvd
Flower Mound TX 75028

Mako Surgical Corp
3365 Enterprise Ave
Weston FL 33331

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 24-255
Howmedica Osteonics Corporation	)	
dba Styker Spine (Allendale, NJ)	)	
Registration # 4-122812	)	
	)	
Stryker Corpiration (Portage, MI)	)	
Registration # 5-122838	)	
Registration # 4-122878	)	
	)	
Stryker Corporation (San Jose, CA)	)	
Registration # 5-122884	)	
Registration # 4-122899	)	
	)	
Stryker Corporation (Flower Mound, TX)	)	
Registration # 5-122879	)	
Stryker Communications, Inc.	)	
Registration # 4-122883	)	
	)	
Mako Surgical Corp (Weston, FL)	)	
Registration # 5-122773	)	
Registration # 4-122772	)	

SUMMARY ORDER

NOW, on this 3rd day of September 2024, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Stryker Corporation ("Applicant"), for application for registration as a manufacturer and a wholesale distributor in the state of Kansas.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On April 9, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Howmedica Osteonics Corporation dba Styker Spine" located at 2 Pearl Court, Allendale, New Jersey ("Applicant's NJ Manufacturer Application").

   a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes," the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas."

   b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 166 unique days from October 4, 2022 to October 31, 2023.

2. On April 11, 2024, the Board received Applicant's application for registration as a non-resident wholesale distributor in the State of Kansas for the distribution facility "Stryker Corporation" located at 6300 S Sprinkle Road, Portage, Michigan ("Applicant's MI Distributor Application").

   a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

   b. On June 12, 2024, Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 231

unique days from May 24, 2023 to May 23, 2024.

3. On April 19, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Stryker Corporation" located at 1941 Stryker Way, Portage, Michigan ("Applicant's MI Manufacturer Application").

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 115 unique days from October 7, 2022 to October 3, 2023.

4. On April 19 and 23, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas ("Applicant's CA Manufacturer Application") and Applicant's application for registration as a non-resident wholesale distributor ("Applicant's CA Distributor Application") for the facility "Stryker Corporation" located at 5900 Optical Court, San Jose, California.

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas from January 3, 2023 to March 3, 2024.

5. On April 19, 2024, the Board received Applicant's application for registration as a non-resident wholesale distributor in the State of Kansas for the distribution facility "Stryker

Corporation" located at 571 Silveron Blvd, Flower Mound, Texas ("Applicant's TX Distributor Application").

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas from January 4, 2023 to March 6, 2024.

6. On April 19, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Stryker Communications, Inc." located at 571 Silveron Blvd, Flower Mound, Texas ("Applicant's TX Manufacturer Application").

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 116 unique days from January 11, 2023 to March 6, 2024.

7. On April 1, 2024, the Board received Applicant's application for registration as a non-resident wholesale distributor in the State of Kansas for the distribution facility "Mako Surgical Corp" located at 3365 Enterprise Ave, Weston, Florida ("Applicant's FL Distributor Application").

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 132 unique days from August 31, 2022 to August 31, 2023.

8. On April 1, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Mako Surgical Corp" located at 3365 Enterprise Ave, Weston, Florida ("Applicant's FL Manufacturer Application"). Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against the application of any manufacturer or wholesale distributor upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Pursuant to K.S.A. 65-1643(g), it shall be unlawful for any person to manufacture any drugs or devices without first obtaining a registration from the Board.

5. Applicant's act of shipping into Kansas as a non-resident wholesale distributor from five unique facilities prior to being registered as a wholesale distributor is a violation of K.S.A. 65-1643(c) and is a basis to take action against Applicant's NJ Distributor Application, Applicant's MI Distributor Application, Applicant's TX Distributor Application, Applicant's CA Distributor

Application, and Applicant's FL Distributor Application pursuant to K.S.A. 65-1627(f).

6. Applicant's act of operating as a non-resident manufacturer in Kansas from five unique facilities prior to being registered as a manufacturer is a violation of K.S.A. 65-1643(g) and is a basis to take action against Applicant's NJ Manufacturer Application, Applicant's MI Manufacturer Application, Applicant's TX Manufacturer Application, Applicant's CA Manufacturer Application, and Applicant's FL Manufacturer Application pursuant to K.S.A. 65-1627(f)(6).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's NJ Distributor Application, Applicant's MI Distributor Application, Applicant's TX Distributor Application, Applicant's CA Distributor Application, Applicant's FL Distributor Application, Applicant's NJ Manufacturer Application, Applicant's MI Manufacturer Application, Applicant's TX Manufacturer Application, Applicant's CA Manufacturer Application, and Applicant's FL Manufacturer Application are hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of $25,000. Applicant has 30 days from the date of this order to pay the fine and the registrations shall be issued upon receipt.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

9/1/2024
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 3rd day of September 2024, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Howmedica Osteonics Corporation
dba Stryker Spine
2 Pearl Ct
Allendale NJ 07401

Stryker Corporation
6300 S Sprinkle Rd
Portage MI 49002

Stryker Corporation
1941 Stryker Way
Portage MI 49002

Stryker Corporation
5900 Optical Ct
San Jose CA 95138

Stryker Corporation
Stryker Communications, Inc.
571 Silveron Blvd
Flower Mound TX 75028

Mako Surgical Corp
3365 Enterprise Ave
Weston FL 33331

Kansas Board of Pharmacy Staff

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Michigan

Parent Company (if any): _____

Corporation Name: Stryker Corporation

Mailing Address: 1741 Stryker Way

City: Portage State: MI Zip: 49002

Telephone: _____ Email: _____

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): K2M, iNC.

Corporation/Organization Name: Stryker Spine, LLC

Mailing Address: 2 Pearl Court

City: Allendale State: NJ Zip: 07401

Telephone: (201) 825-4900 Email: jchan@vbllc.com

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Styker Spine, LLC

Facility Name

Christopher John Tortora

Print Name of Authorized Person Submitting Application

C M

Original signature of Authorized Person (copies or stamps not accepted)

3.17.25

Date

Board Use Only	Date Received: _____ Amount: _____

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
STRYKER SPINE
2 PEARL COURT
ALLENDALE, NJ 07401
Registration Number: 3004024955
FEI Number*: 3004024955
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
STRYKER CORP.[6]
4100 East Milham Ave.
Kalamazoo, MI US 49001
Owner/Operator Number: 1811755[7]

Official Correspondent:
Oonagh Lahiff
2 Pearl Ct
Allendale, NJ 07401
Phone: 001-201-8243302

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 03/10/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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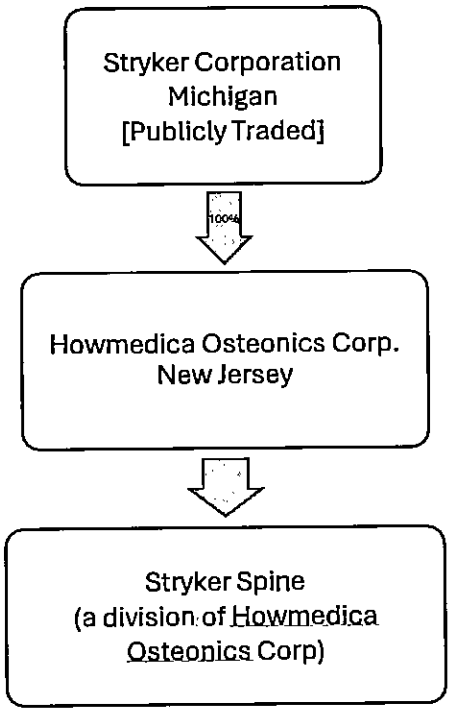
Stryker Spine, LLC

Officer List effective April 1, 2025

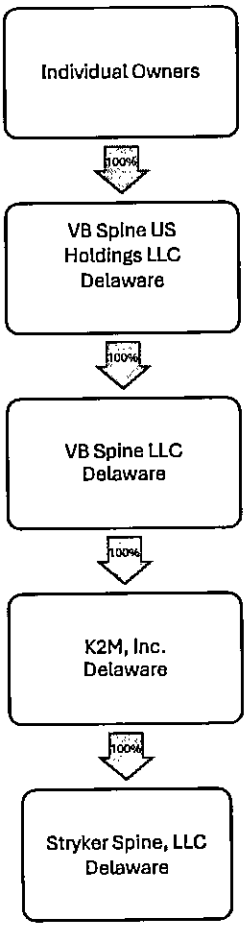
Name	Title
Marc Richard Viscogliosi	co-Chief Executive Officer
John Joseph Viscogliosi	co-Chief Executive Officer
Anthony Gaetano Viscogliosi	co-Chief Executive Officer
Joseph Chan	Secretary

Organizational Chart – Stryker Spine, LLC

Pre-Organizational Chart



Post-Organizational Chart



Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "STRYKER SPINE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE NOT HAVING BEEN CANCELLED OR REVOKED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF FORMATION, FILED THE ELEVENTH DAY OF OCTOBER, A.D. 2024, AT 9:46 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATE IS THE ONLY PAPER OF RECORD, THE LIMITED LIABILITY COMPANY IN QUESTION NOT HAVING FILED AN AMENDMENT NOR HAVING MADE ANY CHANGE WHATSOEVER IN THE ORIGINAL CERTIFICATE AS FILED.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "STRYKER SPINE, LLC" WAS FORMED ON THE ELEVENTH DAY OF OCTOBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5505587 8315

SR# 20251406952

Authentication: 203367776

Date: 04-04-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

CERTIFICATE OF FORMATION
OF
STRYKER SPINE, LLC

The undersigned, being authorized to form a limited liability company under the Delaware Limited Liability Company Act, hereby adopts the following Certificate of Formation for a limited liability company:

FIRST: The name of the limited liability company is "Stryker Spine, LLC".

SECOND: The address of its registered office in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: This Certificate of Formation shall be effective on the date of filing with the Delaware Secretary of State.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this 11th day of October 2024.

/s/ Sherwin Yee
Sherwin Yee, Authorized Person

State of Delaware
Secretary of State
Division of Corporations
Delivered 09:46 AM 10/11/2024
FILED 09:46 AM 10/11/2024
SR 20243924916 - File Number 5505587

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0752551

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☐ wholesaler which conducts business at the following locations in this State:

59 ROUTE 17 S ALLENDALE, NJ 07401-1677

Reg. No.
5003072

STRYKER SPINE
2 PEARL CT
ALLENDALE, NJ 07401-1677

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 04/01/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Meenakshi Luthra	
Fabricant & Fabricant Inc. 1251 Old Northern Boulevard P.O. Box 9004 Roslyn NY 11576	PHONE (A/C, No, Ext): (516) 621-9000	FAX (A/C, No): (516) 621-0092
	E-MAIL ADDRESS: meenakshil@fabricantinsurance.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Hartford Fire Ins. Co.	19682
INSURED VB Spine LLC 505 Park Avenue 14th Floor New York NY 10022	INSURER B :	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** Master '25-'26 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [X] CLAIMS-MADE [ ] OCCUR DEDUCTIBLE: $250,000 RETRO DATE: 04/01/2025 GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			12UGABP7GZ5-037	04/01/2025	04/01/2026	EACH OCCURRENCE	$ 20,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
							GENERAL AGGREGATE	$
							PRODUCTS - COMP/OP AGG	$ 20,000,000
								$
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

K2M, Inc. and its affiliated companies are wholly owned by VB Spine and named under the referenced policy effective 4/1/25.

The policy referenced above covers actual or alleged product defects arising out of VB Spine's negligence in design, manufacturing, or handling products distributed by authorized sales representatives.
Limits are in US Dollars.
Subject to the provisions of the policy, Emergo Europe B.V., as an agent for K2M, Inc. is included as an Additional Insured under the referenced policy to the extent required by the European Authorized Representative Agreement between the parties.

CERTIFICATE HOLDER

Emergo Europe B.V.
Westervoortsedijk 60
Arnhem GE 6827 NLD

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 12BSBJI8878

Application/License No. WH03711

Stryker Spine, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2 Pearl Court, Allendale, NJ 07401 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 8888 East Raintree Drive, Scottsdale, AZ 85260 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

12BSBJI8878

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 2025.

APPLICANT/PRINCIPAL

Stryker Spine, LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Robert Fabricant, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: FOUNDATION RISK PARTNERS CORP
Agency Code: 12-122310

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Robert Fabricant

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 12BSBJI8878
Naming Stryker Spine, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of April 21, 2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2024

CHRISTOPHER **TORTORA**

[redacted]

A Quality Manager with more than 20 years' experience in quality assurance and engineering, including 18+ years' in medical device design and manufacturing. A technical leader with deep experience in regulatory requirements and manufacturing practices. An outstanding communicator and team builder focused on developing talent and driving collaboration with partners. Influential in setting site quality goals and measures to drive improvement.

EXPERIENCE

2022 - PRESENT

SR. DIRECTOR, QUALITY ASSURANCE, STRYKER SPINE

- Sr. Director for Quality Assurance for both the Core Spine and Enabling Technologies Business Units.
- Manage budget for Quality Assurance teams across three sites, Allendale, NJ, Leesburg, VA and Shirley, MA.
- Resource planning, performance, and leadership objective planning for Quality Assurance team, including NC/CAPA, Quality Engineering, Software Quality, Product Safety, Post Market Surveillance, Medical Affairs and Clinical Sciences.
- Leading a team of twenty-four full time Quality professionals.
- Coordinate with strategic Global Quality and Operations and Corporate Shared Services.

2019 - 2022

DIRECTOR, QUALITY ASSURANCE, STRYKER SPINE

- Director for Quality Assurance the Core Spine business Unit.
- Led integration of Quality Assurance activities of Mobius, in Shirley MA,
- Manage budget for Quality Assurance teams across three sites, Allendale, NJ and Leesburg, VA.
- Resource planning, performance, and leadership objective planning for Quality Assurance team, including NC/CAPA, Quality Engineering, Software Quality, Product Safety and Clinical Sciences.
- Coordinate with strategic Global Quality and Operations and Corporate Shared Services.

2018 - PRESENT

SR MANAGER, QUALITY ASSURANCE, STRYKER SPINE

- Sr. Manager for Spine Divisional QA team at both Allendale, NJ and Leesburg, VA.
- Oversight for Advanced Quality Assurance team to support new product development and on-going sustaining activities necessary for continued global growth.
- Oversight for Post Market Surveillance, ensuring compliant and effective investigation and documentation of customer complaints.
- Direct management of Microbiology team supporting new product development, sustaining and remediation efforts.
- Leader of the Quality Assurance workstream for integration of K2M with Stryker Spine Division.
- Manage resources to support execution of product launches, M&A and OEM development projects

- Effective support of external audit activities, through preparation, facilitation and corrective actions.

2017 – 2018

QUALITY MANAGER, STRYKER SPINE

- Manage AQE and Microbiology team resources to support on-going sustaining activities necessary for continued global growth.
- Optimization of procedure for biocompatibility material master file creation and control, validation of OUS parameters for cleaning and sterilization of reusable instruments, improvement and consolidation of instruction for cleaning and sterilization of implants and instruments.
- Manage resources to support execution of product launches, M&A and OEM development projects
- Complete the integration of OBX Quality Management System (QMS) in to the Stryker Spine Quality Management System.
- Effective support of external audit activities, through preparation, facilitation and corrective actions.
- Planned and executed key improvements to enhance the compliance and strength of the Spine divisional microbiology program.

2016 – 2017

SUPPLIER QUALITY MANAGER, STRYKER GLOBAL QUALITY & OPERATIONS

- Managed a team of eight (8) supplier quality engineers and specialists located at both the Stryker Spine Allendale site and our Cestas, France manufacturing facility.
- Developed and deployed strategic goals for supplier management compliance activities.
- Established SICRB to ensure prioritization and proper resourcing of supplier changes.
- Managed resources and led efforts to resolve back order issues to maintain customer service for purchased products and raw materials.
- Managed resources to meet KPI goals for NC/SCAR/CAPA and change control.

2012 – 2015

QUALITY ENGINEERING MANAGER, STRYKER GLOBAL QUALITY & OPERATIONS

- Led a team of seven Quality Engineers providing support for change control, NC/CAPA and process improvement activities at the Mahwah manufacturing site.
- Built a strong QE team by successfully recruiting, coaching and developing talented engineers. Achieved great customer focus by changing team structure and redeploying resources to meet new challenges. Effectively used Gallup 4-Keys Coaching and IDP to create development plans focused on individual strengths and motivations.
- Led Mahwah QA strategic planning efforts, aligning ONV goals and local targets to Mahwah QA Strategic A3. Created MDI tier board metrics to measure daily performance and to expose and track resolution of problems.
- Consistently achieved excellent results in support of external audits as backroom coordinator, management representative and facilitator for corporate, notified body, and regulatory body audits including FDA, BSi and ANSM.
- Maintained a strong influence on local manufacturing and quality results as Mahwah QA representative on ECRB and as Site Head of Quality for NCR approval.
- Implemented Sentinel human error reduction methodologies. Achieved great progress in deployment areas and have imbedded tools into change control and corrective action practices. Rolled out plant-wide human factors orientation and intensive line clearance fundamentals training and for operators and inspectors

- Received the 2013 Mahwah Plant, GQO Quality First Award and 2014 Implants Operations Division, GQO Quality First Award.

2010 – 2012

SUPERVISING SR. QUALITY ENGINEER, STRYKER GLOBAL QUALITY & OPERATIONS

- Led a small team of four (4) quality engineers, providing coaching, performance management and supporting development goals for the team.
- Created a strong collaborative working relationship with operations managers and directors, participating directly in site level quality and operations strategic planning.
- Provided technical support for QMS integration for new acquisitions.
- Collaborated with product support engineering to create the procedure for remediation of legacy products.

2009 – 2010

SR. QUALITY ENGINEER, STRYKER GLOBAL QUALITY & OPERATIONS

- Provided statistical data analysis for risk assessment and process analysis.
- Led FDA remediation activities as the Quality lead for the Operations FDA Readiness SWAT team, managing several consultants to find and eliminate critical quality gaps in manufacturing.
- Successfully led efforts to resolve FDA 483.

2007 – 2009

QUALITY ENGINEER, STRYKER GLOBAL QUALITY & OPERATIONS

- Participated in FDA remediation activities, including development of risk management documents.
- Managed compliance activities and supported sustaining activities for Knee, Hip and Instruments manufacturing cells, including change control, CAPA, calibration and risk management requirements.

2006 – 2007

MANUFACTURING & QUALITY ENGINEER, BIO-CHEM VALVE COMPANY

- Leader for process improvement initiatives including development of process map, FMEA, capability analysis and quality planning.
- Redesigned product components and eliminated non-value-added processes for a cost estimated savings of $53,000 annually. Designed testing automation and data acquisition that result in expansion of diagnostic testing while simultaneously reducing costs by $12,000 per year.

2006 – 2007

MANUFACTURING & QUALITY ENGINEER, BIO-CHEM VALVE COMPANY

- Leader for process improvement initiatives including development of process map, FMEA, capability analysis and quality planning.
- Redesigned product components and eliminated non-value-added processes for a cost estimated savings of $53,000 annually. Designed testing automation and data acquisition that result in expansion of diagnostic testing while simultaneously reducing costs by $12,000 per year.

2004 – 2006

QUALITY ENGINEER, METEM CORPORATION

- Acted as lead quality engineer for new products introduction, responsible for developing inspection methods, control plans, metallurgical analysis and coordination with customers and suppliers.
- Regularly used statistical tools to identify and eliminate causes of failure and to measure the success of ongoing quality initiatives.
- Coordinated the efforts of the inspection, metrology and quality engineering staff to support the needs of manufacturing, engineering and ongoing quality improvement initiatives.

2003 – 2004

QUALITY SUPERVISOR, MARCAL PAPER MILLS

- Supervised a staff of four quality inspectors in the testing lab and incoming inspection office.
- Collaborated with suppliers and service providers to maintain incoming material quality and equipment functionality.
- Coordinated production trials for product improvement and cost reduction.

2002 – 2003

QUALITY SPECIALIST, MARCAL PAPER MILLS

- Performed analysis to discover trends and achieve process refinement and control.
- Worked closely with Marketing, Purchasing and Production departments to develop product requirements.
- Created new and improved existing product testing and auditing procedures.

EDUCATION

MAY 2001

B.S. MECHANICAL ENGINEERING RUTGERS UNIVERSITY

Graduated with Honors

SKILLS AND CERTIFICATIONS

- Human Factors Investigation, Conscientious (2015)
- Global Leadership Training, Stryker (2013)
- CFR-QSIT Certification, Stat-A-Matrix (2012)
- Great Leaders Program, Gallup (2011)
- Six Sigma Greenbelt Training, Somerset County College (2008)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Styker Spine, LLC MDEG License # (if applicable) WH03711

Physical Address 2 Pearl Court

City Allendale State NJ Zip 07401

Mailing Address (if different from physical address) Same as physical

City _____ State _____ Zip _____

Telephone (201) 825-4900 Website _____

Licensing Company Email _____

Section 2: Personal Information

First Christopher Middle John Last Tortora

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 2 Pearl Court

City Allendale State NJ Zip 07401

Telephone [redacted] Email chris.tortora@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		1997 - 2001	
Address	**City**	**State**	**Zip**
57 US Highway 1	New Brunswick	NJ	08901-8554
Diploma/Degree obtained, if any			
BS Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Rutherford Highschool		09/1991 - 06/1996	
Address	**City**	**State**	**Zip**
56 Elliot Place	Rutherford	NJ	07070
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20-pres	[redacted]	[redacted]	NJ	[redacted]
From - To (MM/YY – MM/YY)			State	
07/03-03/20			NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Stryker Spine				From - To (MM/YY – MM/YY): 2017 - Present
Business Address: 2 Pearl Court		City: Allendale	State: NJ	Zip: 07401
Phone: (201) 825-4900	Title: Sr. Director, Quality Assurance			Number of Employed Hours: +6000 Hours
Description of Duties: See attached.				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Tortora, **certify that as the MDEG Administrator for**

Howmedica Osteonics Corp dba Stryker Spine,

that I (initial that you have read and meet the following requirements):

1. CJT Have a high school diploma or its equivalent;
2. CJT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CJT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CJT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Tortora
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6.5.24
Date

Board Use Only	Date Received: 6/24/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Styker Spine, LLC

Pharmacy/Wholesaler License # (if applicable): WH03711

Physical Address: 2 Pearl Court

City: Allendale State: NJ Zip: 07401

Mailing Address (if different from physical address): Same as physical

City: State: Zip:

Telephone: (201) 825-4900 Website:

Licensing Company Email:

Section 2: Personal Information

First: Christopher Middle: John Last: Tortora

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 2 Pearl Court

City: Allendale State: NJ Zip: 07401

Telephone: [redacted] Email: chris.tortora@stryker.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rutgers University		1997 - 2001	
Address	**City**	**State**	**Zip**
57 US Highway 1	New Brunswick	NJ	08901
Diploma/Degree obtained, if any			
BS Mechanical Engineering			
School Name		**From - To (MM/YY – MM/YY)**	
Rutherford Highschool		09/1991 - 06/1996	
Address	**City**	**State**	**Zip**
56 Elliott Place	Rutherford	NJ	07070
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20 - pres	[redacted]	[redacted]	NJ	[redacted]
07/03-03/20			NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Stryker Spine			From - To (MM/YY – MM/YY): 2017 - Present	
Business Address: 2 Pearl Court		City: Allendale	State: NJ	Zip: 07401
Phone: (201) 825-4900	Title: Sr. Director, Quality Assurance		Number of Employed Hours: +6000 Hours	
Description of Duties: See attached.				
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Tortora, **certify that as the designated representative for**

Howmedica Osteonics Corp dba Stryker Spine,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CST I am at least 21 years of age;
3. CST I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CST I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CST I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CST I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CST I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Tortora
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6.5.24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Tortora
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6.5.24
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Bergen

I, Christopher Tortora, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6.5.24
Date

Subscribed and Sworn to before me this 5 day of June, 2024

Lauren P. Nitahara
Notary Public Signature

LAUREN P. NITAHARA
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires 2/12/2026



First Name	Last Name	Business Title	Employee Status Descr Long
Mohamed	Abadrabo	Inventory Control Technician I	Active
Omid	Abbarin	Senior Manager, IT BP	Active
Hakam	Abu Dawwas	Driver	Active
Mohaned	Abujennah	Staff NPI Quality Engineer	Active
Rachel	Achurra	AM, Commercial Ops	Active
Alyssa	Ader	Quality Engineer	Active
Hena	Afshari	Commercial Ops Specialist	Active
Max	Agbayani	Quality Control Inspect. Tech	Active
Katelynne	Agnetti	Medical Education Lead	Active
Bryan	Ahrens	Sr. Sales Representative	Active
Christian	Akers	Sales Representative	Active
Briggs	Akin	Sales Associate	Active
Racquel	Aking	AM, Post Market Surveillance	Active
Mohamed	Alaas	Lead Tech., Engineering RL	Active
Laura	Alders	Inventory Control Tech. III	Active
Sam	ALFIERI	Sales Representative	Active
Teri	Allard	Finance Associate, Invoicing	Active
Richard	Allen	Lead Driver	Active
Shane	Allen	Sales Representative	Active
Morgan	Allin	Supervisor, Quality Control	Active
Matt	Allison	Area Sales Director	Active
Ashley	Almodovar	Technician Loaner I	Active
Tetiana	Alonso	Field Operations Team Leader	Active
Marc	Alperen	Sales Associate	Active
Tony	Alvarenga	Manager; Operations	Active
Patricia	Alvarenga	Finance Specialist, Invoicing	Active
Victor	Alvarenga	Lead, IT Solution Support	Active
Alicia	Ameur	Finance Specialist, Invoicing	Active
Darren	Anders	Sales Associate	Active
Aaron	Anderson	Commercial Ops Associate	Active
Emily	Anderson	Portfolio Associate	Active
Matthew	Angelone	Sales Representative	Active
Brian	Aparo	Regional Sales Manager	Active
Pauline	Apisitpaisarn	Inventory Control Tech. II	Active
Alena	Aranda	Senior Lead, IT Business An.	Active
Eric	Armbruster	Sr. Sales Representative	Active
Craig	Armstrong	SM, Customer Experience	Active
Katie	Armstrong	SM, Education Associate	Active
Rida	Arshad	Senior Advanced Qual. Engineer	Active
Matt	Ashman	AM, Master Data Governance	Active
Martin	Ayers	Associate Manager, R&D	Active
Kole	Ayl	Sr. Sales Representative	Active
Jimmy	Bacon	Regional Sales Manager	Active
Keith	Baker	Sr. Sales Representative	Active
Jerry	Bardol	Sales Associate	Active
Olivia	Bark	Development Engineer	Active
Nicholas	Barka	Sr. Sales Representative	Active
Skip	Barkley	Sr. Spine Specialist	Active
Callen	Barlik	Product Manager	Active
Paget	Barlow	Sales Associate	Active
Liam	Barnes	Staff Engineer	Active
Matthew	Bartlow	Sr. Sales Representative	Active
Mishu	Barua	Project Engineer	Active
Jack	Bates	Spine Specialist	Active
Samay	Bayat	Quality Control Technician I	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Anastasia	Bazil	Manager, Sales Operations	Active
Jeremy	Beavin	Supply Planner	Active
Joel	Beavin	Senior Field Count Associate	Active
Emmet	Bell	Sales Representative	Active
Tondrae	Bell SR	Driver	Active
Damon	Belloni	Principal Quality Systems Sp.	Active
Caity	Benham	Contract Activation Analyst	Active
Sara	Benner	Inventory Control Technician I	Active
Ashley	Bergen-Stewart	Lead Analyst, Data Analytics	Active
Michael	Berlin	Sr. Sales Representative	Active
Obrien	Berry	Sr. Sales Representative	Active
Nick	Betts	Field Operations Team Leader	Active
John	Bewley	CNC Programmer/Machinist	Active
Aparna	Bharath Kumar	Senior Staff Data Analyst	Active
Brian	Bickell	Regional Sales Manager	Active
Jacob	Birkholz	Staff Quality Data Engineer	Active
Pragya	Bista	SM, Regulatory Affairs	Active
Rakshya	Bista	Program Manager, CQR	Active
Petra	Blake	Commercial Ops Associate	Active
Madison	Boman	Lead Analyst, Sales Operations	Active
Alyse	Borelli	Manager, Clinical Affairs	Active
Natalie	Bost	Finance Specialist, Invoicing	Active
Thomas	Bowe	Spine Specialist	Active
Zach	Bowen	Sr. Sales Representative	Active
Clint	Boyd JR	SM, Product Engineering	Active
Pamela	Brenes	Quality Systems Specialist	Active
Mario	Brito	Loaner Technician II	Active
Rebecca	Brooks	Director, Downstream Marketing	Active
George	Brooks JR	Regional Sales Manager	Active
Morgan	Brophy	Sr. Staff R&A Sp.	Active
Gregory	Brown	Sr. Program Mgr., PMO & Strat.	Active
Shelly	Brown	Sr. Spine Specialist	Active
Molly	Brown	Clinical Program Manager	Active
Tim	Brown	Sales Associate	Active
Jenny	Brusehaber	Commercial Ops Team Lead	Active
Blake	Buchanan	Lead Analyst, Finance	Active
Peter	Budway	CNC Programmer/Machinist II	Active
Nick	Buras	Commercial Ops Specialist	Active
Katie	Burch	Commercial Ops Specialist	Active
Meghan	Burns	Portfolio Manager	Active
Kurt	Busscher	Sr. Sales Representative	Active
Erin	Butler	Senior Marketing Associate	Active
Mason	Butler	Team Member, Driver	Active
Kevin	Cabatu	Field Operations Technician II	Active
Andrew	Calcaterra JR	Sr. Advanced Quality Engineer	Active
Lauren	Caldwell	AM, Field Ops	Active
Eric	Campbell	Sr. Sales Representative	Active
Michael	Campbell	Senior Manager, Sourcing	Active
John	Campe	Product Packager I	Active
Neil	Campe	Inventory Control Specialist	Active
Thomás	Canale	Area Vice President	Active
Jose	Canchola	Sr. Spine Specialist	Active
Christina	Cannon	Spine Experience Program Mgr.	Active
Derek	CAPPS	Sr. Sales Representative	Active
Brenna	Carbone	Quality Engineer, Post Market	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Megan	Carnes	SM, Quality Assurance	Active
Callie	Carpenter	Staff Engineer	Active
Scott	Carpenter	Loaner Specialist	Active
Raven	Carter	Senior Clinical Data Sp.	Active
Justin	Casey	Spine Specialist	Active
Cathy	Castle	Finance Associate, Invoicing	Active
Ashlynn	Catalan	Senior Analyst, Data Analytics	Active
Eric	Cecco	Staff Engineer	Active
Jasmine	Cerpas	Lead HR Representative	Active
Sam	Chaar	Sr. Staff Eng., Advanced Ops	Active
Jchan@Vbllc	Chan	SVP, General Counsel	Active
Sathya	CHANDRN	Senior Quality Systems Sp.	Active
Katelyn	Chase	Director, Sales Operations	Active
Jeffrey	Chavez	Driver	Active
Lisa	Chen	Spine Specialist	Active
Danilo	Ching	Loaner Technician III	Active
Theo	Choi	Senior Staff Engineer	Active
Nuzhat	Chowdhury	Senior Microbiologist	Active
Bryan	Clancy	Sr. Sales Representative	Active
Alessandra	Clark	Sr. Clinical Contract Assoc.	Active
Tyler	Clarkson	Project Manager, Advanced Ops	Active
Izzy	Clavenna	Sales Associate	Active
Andrew	Clavio	Inventory Control Tech. II	Active
Zachary	Clifford	Sales Representative	Active
Chelsea	Coburn	Regional Sales Manager	Active
Karen	Colletti	Finance Specialist, Invoicing	Active
Colton	Collins	Sales Associate	Active
Matt	Collins	Regional Sales Manager	Active
Sawyer	Collins	Production Team Leader	Active
Terry	Connor	Senior Supervisor, Production	Active
Lorie	Continelli	Sr. Director, R&D	Active
Scott	Converse	Sr. Sales Representative	Active
Angie	Cooke	Senior Coordinator	Active
Shannon	Cool	Fulfillment Technician II	Active
Brooks	Cooper	Loaner Technician I	Active
Reese	Cooper	Staff Quality Engineer	Active
Elisha	Corbin	Field Operations Technician II	Active
Ryan	Corley	C&E Lead - Bioskills Lab	Active
Bill	Corpas	Sales Representative	Active
Daryl	Creamer JR	Product Packaging Specialist	Active
Dylan	Creasey	Spine Specialist	Active
David	Cremin	Sales Representative	Active
Chad	Croteau	Spine Specialist	Active
Cesar	Cubillos	Data Engineer	Active
Brian	Curry	Associate Manager, Sourcing	Active
Brittney	D'Aloia	Sr. Supervisor, Commercial Ops	Active
Jackson	Dana	Inventory Control Technician I	Active
Sharon	Dana	Finance Specialist, Invoicing	Active
Sevack	Danadian	Senior Quality Systems Sp.	Active
Kristina	Daoud	Senior Regulatory Affairs Sp.	Active
Sarah	Darnell	Senior PMS Analyst	Active
Emily	DAVIDSON	Senior Portfolio Associate	Active
Jeremy	Davis	Sr. Sales Representative	Active
Petra	DAVIS	Sales Representative	Active
Angie	Dawson	Senior EHS Technician	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Jason	Dawson	Prod. Pckg. II, Pckg.- Skilled	Active
Ryan	Dawson	Quality Control Inspector II	Active
Greg	Day	Assoc. Supervisor, Production	Active
Caity	De Angelus	Project Manager, Advanced Ops	Active
Kaylah	De Gree	AM, Downstream Marketing	Active
Pat	DeLong	Area Vice President	Active
Trinity	Denholm	Sales Representative	Active
Larry	Dennis	AM, Product Engineering	Active
Luis	Depina	Field Operations Technician II	Active
Marco	Di Rocco	Field Operations Technician II	Active
Tanc	DICKENS	Sr. Sales Representative	Active
Derek	Diehl	Spine Specialist	Active
Michael	Dill	Senior Staff NC/CAPA Sp.	Active
Caleb	DIPRETE	Sr. Process Dev. Engineer	Active
Brent	Dlugach	Director, Strategic Sales	Active
Jeff	Dobies JR	Production Team Lead	Active
Mike	Doerr	Regional Sales Manager	Active
Michael	Doleglewitz	Staff Engineer, Engineering	Active
Lori	Dombrowski	Senior Staff Designer	Active
Conor	Donohue	Sr. Sales Representative	Active
Andy	Dorich	Spine Specialist	Active
Teresa	Driscoll	Sales Coordinator	Active
Kelly	Dye	Finance Associate, Invoicing	Active
Miguel	Echarte	Area Sales Director	Active
Sean	Edson	Sales Representative	Active
Carl	Edwards	Reverse Technician I	Active
Onika	Edwards	Inventory Control Tech. II	Active
Drew	Eibner	Sr. Sales Representative	Active
Allison	Elkins	Inventory Control Tech. II	Active
Riley	Elkins	Inventory Control Technician	Active
Sydnee	Elkins	Loaner Technician II	Active
Patrick	Ennis	Regional Sales Manager	Active
Matt	Estrada	Production Team Lead	Active
Latonya	Evans	Quality Systems Specialist	Active
Sedale	Evans	Director, Manufacturing	Active
Samantha	Fatkin	Sales Associate	Active
Esther	Fatokun	Contract Perform. Mngt. Anlst.	Active
Keith	Fava	Director, PMO	Active
Taylor	Fawcett	Sales Associate	Active
Alexander	Feliu	Inventory Control Technician I	Active
Shianna	Fenner	Comm. Ops Team Lead, Global	Active
Adriana	Feraco	Product Packager II	Active
Hope	Ferdinando	Staff Advanced Quality Eng.	Active
Mferguson@Vbllc	Ferguson	Executive Assistant	Active
Jessica	Ferrell	Finance Associate, Invoicing	Active
Hannah	Floyd	Commercial Ops Associate	Active
Cynthia	Forgione	Finance Specialist, Invoicing	Active
Nicole	Foti	AM, Meeting Planning and Even.	Active
Walter	Fraidenburg	Sr. Sales Representative	Active
John	Frank	Sr. Sales Representative	Active
Amy	Frankenberger	Senior Manager, Finance	Active
Catherine	Franzen	Sales Coordinator	Active
Brian	Frazier	Spine Specialist	Active
Joseph	Fredericks	Staff Engineer	Active
David	Freeland	Inventory Control Technician	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Danny	Friedman	Field Scheduler	Active
Cristian	Fuentes	Driver	Active
Alex	Funck	CNC Programmer/Machinist	Active
Shelly	Furman	Finance Specialist, Invoicing	Active
Brittany	Gadigian	Senior Staff Advanced QE	Active
Michael	Gaintner	Senior Director, PMO	Active
Michaela	Galati	Data Analyst	Active
Aaron	Galvan	Field Operations Technician II	Active
Marco	Galvez	Field Operations Technician I	Active
Tennie	Gandara	Marketing Communications Lead	Active
Cori	Garcia	Portfolio Manager	Active
Craig	Garcia	Sr. Spine Specialist	Active
Nicholas	Gardner	Spine Specialist	Active
Graham	Garlasco	Sales Representative	Active
Isabel	GARZA	Staff Regulatory Affairs Sp.	Active
Jessie	Garza	Sr. Sales Representative	Active
Jalen	Gaudet	Delivery Driver	Active
Jack	Gaylord	Sales Associate	Active
Daniel	Genovese	Senior Staff Engineer	Active
Zachary	George	Spine Specialist	Active
Tashan	GILLIAN	Sr. Field Inv. Coordinator	Active
Brian	Gillis	Senior Field Count Associate	Active
Scott	Gilson	Sales Associate	Active
Cgioffre@Vbllc	Gioffre	Director BD & Transformation	Active
Joseph	Giordano JR	Senior Staff Engineer	Active
Lauren	Gittelman	Project Manager, Planning	Active
Andrew	Gladden	Strategic Sales Manager	Active
Jason	Glynn	Regional Sales Manager	Active
Daniel	Godsil	Sales Representative	Active
Satchel	Gomez Driscoll	Sales Representative	Active
Jesus	Gongora Rocha	Inventory Control Tech. II	Active
Torre	Goodman	Trusted Advisor	Active
Sgormick@Spinebiopharma	Gormick	Executive/Personal Assistant	Active
Christal	Gotimer	Staff Engineer, Advanced Ops	Active
Tiya	Grabowski	Fin. Representative, Invoicing	Active
Shawn	Graham	Manager, Upstream Marketing	Active
Beau	Gray	Sr. Sales Representative	Active
Michael	Greco	Staff Qual. Eng., Post Market	Active
Adrielle	Green	Associate Manager, Finance	Active
Natreal	Green	Field Operations Technician I	Active
Steven	Greendyk	Senior Staff Engineer	Active
Jeffrey	Greengrass	Sr. Sales Representative	Active
Kristin	Greenquist	Sales Representative	Active
Megan	Griffin	Senior Staff Medical Writer	Active
Jamie	Griffith	Assoc. Project Mgr. Prod. Eng.	Active
Michael	Grutkowski	AM, Commercial Ops	Active
Hannah	Gurnavage	Staff Quality Systems Sp.	Active
Christopher	GUTMAN	Sr. Sales Representative	Active
William	Guzman	Machinist II	Active
Quera	Gwaltney	Regulatory Affairs Analyst	Active
Effa	Gyamfi	Clinical Quality Associate	Active
Kelly	Haddox	Lead TA Business Partner	Active
Ailon	Halleyesus	Staff Engineer	Active
Luke	Hains	Spine Specialist	Active
Joseph	Hall	Strategic Sales Manager	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Jim	Ham	Director, Product Engineering	Active
Wael	Hamade	Sr. Sales Representative	Active
Greg	Hand	Field Operations Team Leader	Active
Jim	Harding SR	Sr. Sales Representative	Active
Benjamin	HARPER	Set Assembly Technician II	Active
Allison	Harris	Staff Engineer	Active
Cheston	Harris	Sr. Sales Representative	Active
Austin	Harrison	Commercial Ops Specialist	Active
Darryl	Harrison	Field Operations Technician I	Active
Aaron	Hartlove	Inventory Control Tech. III	Active
Todd	Harvey	Commercial Ops Associate	Active
Basma	Hassan	Quality Engineer	Active
Derek	Hasselhoff	Sr. Sales Representative	Active
Brett	Hawken	Sr. Sales Representative	Active
Hannah	Heberle-Rose	Project Manager, PMO	Active
Corey	Heinz	Sr. Sales Representative	Active
Jacob	Heinz	Sr. Sales Representative	Active
Darlene	Hess	Receiving Technician I	Active
Jack	Higgins	Sales Associate	Active
Jason	Hill	Commercial Ops Associate	Active
Katie	Hill	Sales Associate	Active
Jared	Hocker	Sales Associate	Active
Nicole	Hodgson	Finance Lead, Invoicing	Active
Bill	Holbrook	Sr. Sales Representative	Active
Jordan	Holder	Senior Staff Engineer	Active
Chloe	Holland	Spine Specialist	Active
Katherine	Hollar	Senior Development Engineer	Active
Tim	Holtz	Director, Sourcing	Active
Maegan	Hosner	Commercial Ops Associate	Active
Drew	Howard	Regional Sales Manager	Active
Taylor	Hubert	Commercial Ops Specialist	Active
Donald	Huckaba	Sr. Director, Commercial Ops	Active
Bryan	HUFFAKER	Sales Representative	Active
Guy	Hughes	Senior Director, IT BP, Spine	Active
Niki	Infantino	Manager, HRBP	Active
David	Irwin	Director, IT Business Partner	Active
Landon	Irwin	Inventory Control Technician I	Active
Jessica	Iwinski	Sr. Sales Representative	Active
Eva	James	Senior Regulatory Affairs Sp.	Active
June	Jeffers	Marketing Coordinator Lead	Active
Evan	Jenkins	Supervisor, Production	Active
Dane	Johannessen	Senior Staff Engineer	Active
Curley	Johnson	Sr. Sales Representative	Active
Darren	Johnson	Sales Associate	Active
Ethan	Johnson	Sr. Sales Representative	Active
Jim	Johnson	Sr. Sales Representative	Active
Joshua	Johnson	VP, General Mgr., Core Spine	Active
Connor	Jones	Sr. Engineer, Manufacturing	Active
Diana	Joseph	Product Manager	Active
Daniel	Journey	Sales Associate	Active
Sachie	Kakehi	Staff Engineer	Active
Margarita	Karan	SM, Post Market Surveillance	Active
Adam	Kastner	Sr. Sales Representative	Active
Jack	Keiser	Sales Associate	Active
Matthew	Kelleher	Mgr., Post Market Surveillance	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Amber	Kelley	Sales Representative	Active
Amy	Kennedy	Senior Manager, Finance	Active
Samantha	Keough	Commercial Ops Associate	Active
Jacob	Key	Development Engineer	Active
Sherry	Khan	Commercial Ops Specialist	Active
Grayson	Kilburn	Marketing Associate	Active
Michael	Killam	Sr. Sales Representative	Active
Brian	Kim	Sr. Process Eng., Advanced Ops	Active
John	Kish	Supervisor, Machine Shop	Active
Jessi	Kissner	Assoc. Medical Education Mgr.	Active
Edward	Knoll	Sr. Sales Representative	Active
Reese	KOBUROV	Sales Associate	Active
Marta	Koutsogiannis	Staff Qual. Eng., Post Market	Active
Becky	Kovel	Field Count Coordinator II	Active
Scott	Koysh	Sr. Group Manager, Engineering	Active
Caleb	Krantz	Spine Specialist	Active
Madi	Kraus	Commercial Ops Specialist	Active
Dylan	Kressley	Receiving Technician I	Active
John	Kubia	Field Count Coordinator II	Active
Brian	Kunes	Senior Staff Engineer	Active
Katharina	Kuron	Senior Coordinator, QC	Active
Anthony	LaBush	Lead, IT Business Analyst	Active
Dipan	Lad	Principal Sp., R&A	Active
Melissa	Lahman	Finance Lead, Invoicing	Active
Daniel	Laidler	Loaner Technician III	Active
Sydney	Lane	Sr. Sales Representative	Active
Brittany	Lang	Senior Staff Engineer	Active
Brandon	Langley	Demand Planner	Active
Brad	Larson	Sr. Med. Educ. Program Mgr.	Active
Kyle	Layman	Supply Planner	Active
Chad	Lazzell	Quality Control Specialist	Active
Matthew	Leach	Commercial Ops Associate	Active
Alvin	Lee	Lead Data Analyst	Active
Katrina	Lee	Sr. Sales Representative	Active
Beth	Lee	Lead Analyst, PMO	Active
Lee	Levin	Sr. Sales Representative	Active
Xiao	Lin	Sr. Staff Eng., Qual. Assuran.	Active
Draco	Lincoln	Workshop Coordinator	Active
Samiyah	Lincoln	Associate Supervisor, Prod.	Active
Hui	Liu	Principal Microbiologist	Active
Thomas	Livoti III	Inventory Control Tech. II	Active
Sara	Logsdon	Spine Specialist	Active
Silvana	LoNano	Project Manager, QMS	Active
Kennedy	Long	Sr. Sales Representative	Active
Fiorella	Lopardo	Staff Regulatory Affairs Sp.	Active
Laticia	Lopez	Senior Supervisor, Field Ops	Active
Jeferson	Lopez Medina	Field Operations Technician II	Active
Anthony	LoRusso	Sr. Sales Representative	Active
Tia	Lowe	Sr. Spine Specialist	Active
Diana	Luna	Driver	Active
Binh	Luu	Product Packager I	Active
Dung	Luu	Product Packager II	Active
Jeremy	Luu	Sr. Sales Representative	Active
Kyle	Lysek	Field Operations Technician II	Active
Sean	Maag	Sr. Sales Representative	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Thomas	Mackenroth	Sr. Sales Representative	Active
Piotr	Mackowski	Lead Prototype Machinist	Active
Ed	Macy	Sr. Dir., Customer Excellence	Active
Aaron	Madrid	Spine Specialist	Active
Francoise	Makon	Quality Control technician II	Active
Christina	Mangione	Sr. R&A Sp., PMS	Active
Stephen	Marck	Sr. Sales Representative	Active
Mike	Marden	SM, IT Service Delivery	Active
Steven	Marrone	SM, Commercial Analytics	Active
Alexandra	Martin	Sales Associate	Active
Caylin	Martin	Commercial Ops Associate	Active
Emma	Martin	Sales Representative	Active
Jeremy	Martinez	Sales Representative	Active
Drayke	Mash	Team Leader, Production	Active
Nate	Mast	Sr. Sales Representative	Active
Agustin	Mata	Sales Representative	Active
Claire	Mayers	Manager, Quality Assurance	Active
John	Mayor	Vice President, C&E	Active
John	Mazza	Sales Associate	Active
Lawson	McArthur	Sales Associate	Active
Larry	McClintock	Senior Staff Designer	Active
Kaitlin	McClymont	Sr. Staff Eng., Eng.Ing	Active
Michael	McCormack	Loaner Technician I	Active
Tyler	McCullough	Fulfillment Technician II	Active
Evelyn	McEnaney	Loaner Technician III	Active
Denise	McIntyre	Finance Specialist, Invoicing	Active
Sydnie	McQueen	Fin. Representative, Invoicing	Active
Jordan	McTeague	Inventory Control Technician I	Active
Brian	Meagher	Sales Representative	Active
Brian	Meerholz	Sales Representative	Active
Komal	Mehta	Sr. Process Dev. Eng. Adv. Ops	Active
Trevor	Melton	Lead Technician, Engineering	Active
Stephanie	Mendez Ramirez	Workshop Coordinator	Active
Nathaniel	Mendoza	Inventory Control Tech. II	Active
Reynaldo	Mendoza	Field Operations Technician II	Active
Andrew	Mermer	Commercial Ops Specialist	Active
Dave	Merritt	Sr. Sales Representative	Active
Jana	Metcalf	Regional Sales Manager	Active
Joseph	Meyer	Staff Engineer	Active
Dmeyler@Gmail	Meyler	Associate General Counsel	Active
Deedee	Michaux	Sr. Sales Representative	Active
Curtiss	Miller	Sr. Staff Eng., Advanced Ops	Active
Daniel	Miller	Sales Representative	Active
Liz	Miller	Development Engineer	Active
Jesse	Miller	Manager, Demand Planning	Active
Robert	Millner	Associate Manager, Sourcing	Active
Sandra	Mills	Finance Specialist, Invoicing	Active
Tyler	MILLS	Team Lead, Field Count	Active
Bryan	Milz	Senior Staff Designer	Active
Alexia	Miquel	Sales Associate	Active
Kara	Miyasato	Sr. Director, Marketing	Active
Aarti	Mohan	Engineering Mgr., Advanced Ops	Active
Nmolina@Vblic	Molina	Receptionist and Office Manage	Active
Benjamin	MOORE	Sales Representative	Active
Jennifer	Moore	Sr. Manager, Prod. Engineering	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Jesse	Moore	Manager, Intellectual Property	Active
Sarah	Moore	Sr. Med. Educ. Program Mgr.	Active
Brooke	Moran	Commercial Ops Associate	Active
Shraddha	More	Sr. Staff R&A Sp.	Active
Taylor	Moretti Wolfe	Sr. Sales Representative	Active
Randic	Morillo	Sr. Sales Representative	Active
Paige	Morrissey	Sales Representative	Active
William	Mount	Facilities Manager	Active
Steven	Murphy	Program Manager, PMO	Active
Erin	Musau	Portfolio Manager	Active
Madeline	Myers	Sr. Program Mgr. Strat. Mrktg.	Active
Heather	Nafe	Sales Representative	Active
Shawn	Nash	Production Team Leader	Active
Adam	Naymick	Sr. Sales Representative	Active
Peter	Nechvatal	Regional Sales Manager	Active
Dusty	Needham	Chief DPO, Design Controls	Active
Adam	NEITHARDT	Sr. Sales Representative	Active
Geoffrey	Nelson	Regional Sales Manager	Active
Slavka	Nethercott	AM, Quality Management Systems	Active
Dana	Nettles	AM, Med. Affairs, PMS	Active
Hoai	Nguyen	Product Packager I	Active
Bryon	Nicholson	Senior Manager, Sourcing	Active
Lauren	Nitahara	Sr. Staff R&A Sp.	Active
Crystal	Njoku	Quality Control Technician	Active
Michael	Nocera	Spine Specialist	Active
Renee	Norby	Staff Regulatory Affairs Sp.	Active
Talsiya	Novopachennala	Sr. Staff R&A Sp.	Active
David	Nuckley	SM, R&D Test Engineering	Active
Reece	Nuckols	Sales Associate	Active
Doug	Oakes	Sr. Sales Representative	Active
Todd	Oakes	Sales Representative	Active
Joel	Obiri	Lead Financial Analyst	Active
Maureen	O'Brien	Staff Medical Writer	Active
Alexis	Ocampo	Field Operations Technician I	Active
Leopoldo	Ocampo	Driver	Active
Arnold	Ochoada	Quality Control Tech III	Active
Niall	O'Farrell	Sr Program Manager, PMO	Active
Laurie	Ogden	Senior Analyst, Data Analytics	Active
German	OLIVO-QUEZADA	Driver	Active
Lillian	Olsen	Sr. Director, HR	Active
Josh	Olson	AM, Supply Planning	Active
Siobhan	O'Malley	Sr. R&A Sp., PMS	Active
Jackie	ONeill	Spine Specialist	Active
Javier	Orellana Leon	Associate Supervisor, Prod.	Active
Tim@Vblic	Ormsby	Associate General Counsel	Active
Max	Ozer	Spine Specialist	Active
Samuel	Painter	Production Team Leader	Active
Erin	Palena	Manager, Advanced Operations	Active
Duncan	Palmer	Manager, PMO & Contin. Improv.	Active
Tee	Pamon JR	Staff Regulatory Affairs Sp.	Active
Nimisha	Pant	Associate PM, Advanced Ops	Active
Karen	Pappas	Finance Specialist, Invoicing	Active
Raffaele	Parisi	Sr. Sales Representative	Active
Andrew	Parker	Quality Control Technician II	Active
Shane	Parkinson	Sr. Sales Representative	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Aakash	Patel	Sales Associate	Active
Nicholas	Pereira	Field Operations Technician II	Active
Corina	perez	Field Operations Technician I	Active
Nicholas	Perez	Loaner Specialist	Active
Andrew	Perkins	Fulfillment Technician III	Active
Jeff	Perlmutter	Area Sales Director	Active
Donna	Perry	AM, Medical Education Support	Active
Matt	Persinger	Machine Shop Team Leader	Active
Toby	Pickens	Sr. Spine Specialist	Active
Manoj	Pillai	Sr. Sales Representative	Active
Ian	Pincus	Sr. Sales Representative	Active
Cynthiaisabel	Pineda Ramos	Inventory Control Tech. II	Active
Lauren	Pinkney	Associate Manager, HRBP	Active
James	Pinto	Regional Sales Manager	Active
Candace	Piper	Lead Sp., Professional Affairs	Active
Andrew	Polyack	Field Scheduler	Active
Spencer	Popejoy	Sr. Staff Engineer	Active
Purna	Prakash	Senior Supply Planner	Active
Abby	Prescott	Sales Associate	Active
David	Pyburn	Sales Representative	Active
Kevin	Quinn	Staff Eng., Process Eng.Ing	Active
Michelle	Quinones	Sr. Sp., Professional Affairs	Active
Miguel	Quinones	SA, Financial Controls	Active
Agustin	Quintana	Director, Product Development	Active
Calogero	Ramirez	Staff Engineer, Advanced Ops	Active
Johnathan	Ramirez	Product Packager II	Active
Marci	Ramos	Commercial Ops Associate	Active
Hiral	Rana	Mgr., Integrated Bus. Plan.	Active
Adrian	Razeghi	Financial Analyst	Active
Louis	Redondo	Sr. Sales Representative	Active
Rachel	Rehl	AM, Regulatory Affairs	Active
Kirsten	Reinhold	SM, Regulatory Affairs	Active
Matthew	Remick	Inventory Control Tech. II	Active
Lamia	Reynolds	Loaner Technician I	Active
Tiffany	Riad	Sr. Mgr., Contracts & Pricing	Active
Christina	Rice	Senior Development Engineer	Active
Kate	Richards	Finance AM, Invoicing	Active
Pete	Richter	Manager, IT Business Analysis	Active
Justin	Riley	Sr. Supply Planner	Active
Catherine	Rivera	Senior Ops Quality Analyst	Active
Brendan	Roberts	Sales Associate	Active
Dwight	Roberts II	Workshop Coordinator	Active
Scott	Robinson	SM, Downstream Marketing	Active
Chris	Rodgers	Field Operations Team Leader	Active
Cameron	Rodrigo	Director, Advanced Operations	Active
Eric	RODRIGUEZ	Staff Engineer	Active
Ian	Rodriguez	Commercial Ops Specialist	Active
Megan	Rodriguez	Fin. Representative, Invoicing	Active
Trevor	Roenick	Sr. Sales Representative	Active
Lindsay	Rohr	Senior Manager, Commercial Ops	Active
Raquel	Rojas	Finance Associate, Invoicing	Active
Joseph	Romano	Marketing Communications Lead	Active
Eric	Rooney	AS, Field Operations	Active
Madison	Ross	Lead Strat. Enablement Analyst	Active
Emily	Rossle	AM, Data Analytics	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Lee	Rouss	Commercial Ops Specialist	Active
Kevin	Rowe	Sr. Sales Representative	Active
John	Roy	Sales Representative	Active
Aaron	Rubio	Regional Sales Manager	Active
Evan	Ruggles	Sr. Field Inv. Coordinator	Active
John	Russell	Staff Regulatory Affairs Sp.	Active
Emily	Russo	Senior Portfolio Manager	Active
Dorothy	Rutherford	Set Assembly Technician III	Active
Marcus	Rutherford	Reverse Logistics Tech. III	Active
Anthony	Ryan	Senior Staff Engineer	Active
Jason	Ryznar	Sr. Sales Representative	Active
Samuel	Saavedra	Contract Activation Analyst	Active
Carlota	Sagarduy	Intern, Engineering	Active
Krystal	San Miguel	Associate Supervisor, Finance	Active
Jessica	Sanchez	Assoc. Manager, Advanced Ops	Active
Ralph	Santa Ana	Driver	Active
Blas	Santiago	Field Operations Team Lead	Active
Adrienne	Saraceni	Dir., Qual. Management Systems	Active
Jennifer	Sayama	Lead Analyst, Sales Operations	Active
Korie	Schmidt	Field Scheduler	Active
Laura	Scholl	Principal R&A Sp.	Active
Tyler	Schwarz	Sales Associate	Active
Sara	Schweitzer	Lead TA Business Partner	Active
Gail	Scott	Quality Control Technician III	Active
Hadley	Scott	Project Manager, PMO	Active
Jahsee	Sele	Product Packager I	Active
Wannie	Sele	Production Team Lead	Active
William	Sele	Quality Control Technician III	Active
Benjamin	Shafer	SM, Supply Planning	Active
Hetal	Shah	Lead Rebate Analyst	Active
Ali	Sharifi-Mehr	Chief Engineer	Active
Marc	Shea II	Reverse Logistics Tech. III	Active
Kim	Shebest	Executive Assistant	Active
William	Sheehan	Regional Sales Manager	Active
James	Sherman	Regional Sales Manager	Active
Robert	Simpson	Sales Associate	Active
Travis	Sines	Loaner Technician II	Active
Neeta	Singh	Senior Marketing Associate	Active
Margaret	Smarzewski	Sales Education Training Mgr.	Active
Jolanda	Smedley	Senior Field Count Associate	Active
Cristy	Smith	Employee and CEL	Active
Daniel	Smith	Loaner Specialist	Active
Katie	Smith	Inventory Control Tech. II	Active
Samantha	Smith	Quality Engineer, Post Market	Active
Chip	Smith JR	Regional Sales Manager	Active
Damian	Sobrevilla	Senior Staff Engineer	Active
Megan	Sochanski	Sr. Eng., PMS	Active
Zinoviy	Sosnov	Lead Prototype Machinist	Active
Daniel	Spang	Sr. Sales Representative	Active
Michael	Spies	Associate Manager, R&D	Active
James	Stapleton	Field Operations Team Leader	Active
King	Starks II	Senior Supervisor, Field Count	Active
Jeremiah	Staubs	Senior Process Improvement Sp.	Active
Brent	Steele	Sr. Sales Representative	Active
Barry	Stein	Sr. Sales Representative	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Tyler	Stevens	Sales Representative	Active
Jakob	Stevenson	Sr. Process Dev. Eng. Adv. Ops	Active
Lauren	Stewart-Ebert	Staff Medical Writer	Active
Adrienne	Stone	Lead QC Coordinator	Active
Diana	Stonehouse	Receptionist CE Coordinator	Active
Nathan	Stotts	Area Vice President	Active
Sarah	Stover	Sales Associate	Active
Daniel	Strancar	Sales Associate	Active
Colleen	Sullivan	Dir., Market Int. & Strat.	Active
Mary	Sullivan	Senior Operations Coordinator	Active
Mclain	Sullivan	Inventory Control Tech. II	Active
Annie	Sun	Product Packager III	Active
Margo	Suryanaga	AM, Data Science & Engineering	Active
Sandra	Suryanto	Finance Associate, Invoicing	Active
Teddy	Sweeney	Sr. Sales Representative	Active
Shea	Sweeney	Director, Integrated Planning	Active
Mark	SWISHER	Sales Representative	Active
Sheraz	Tariq	Sr. Proj. Mgr. New Prod. Dev.	Active
Daniel	Tavani	Director, Business Transform.	Active
Diana	Tavenner	Quality Control Technician II	Active
Brian	Taylor	Sr. Sales Representative	Active
Jake	Taylor	Sales Representative	Active
Nico	TAYLOR	Sales Associate	Active
Olivia	Taylor	Sales Representative	Active
Valerie	Tighe	Staff Engineer	Active
Price	Timmerman IV	Sr. Sales Representative	Active
Jared	Tiso	Sr. Spine Specialist	Active
Brian	Tomasello	Sr. Spine Specialist	Active
Matt	Tomasello	Sr. Sales Representative	Active
Jose	Torres	Sales Representative	Active
Chris	Tortora	Sr. Director, Qual. Assurance	Active
Terrence	Tracey JR	Sr. Sales Representative	Active
Gervin	Trejos	Driver	Active
Andrew	Trione	Lead Analyst, Finance	Active
Ray	Tsang	Staff Quality Engineer	Active
Dreyfus	Tuazon	Product Packaging Specialist	Active
Joshua	Tuparan	Loaner Specialist	Active
Annemarie	Valentine	Workshop Coordinator	Active
Gina	Van Natten	Principal Marketing Manager	Active
Blair	van't Hoff	Spine Specialist	Active
Andrea	Vargas-Mark	Manager, PMO	Active
Rene	Vega II	Sr. Sales Representative	Active
Todd	Venema	Sales Associate	Active
Kevin	Vergara	Commercial Ops Associate	Active
Noelle	Verhoog	Senior Quality System Sp.	Active
Alysse	Vindeed	Staff R&A Sp., PMS	Active
Justice	Virbalis	Team Member, Driver	Active
Jake	Vitulli	Lead Field Inv. Coordinator	Active
Simona	Voic	Program Director, R&A	Active
Cole	VonHandorf	Sales Associate	Active
Amanda	Wacaster	Finance Associate, Invoicing	Active
Sandra	Walker	Associate Supervisor, Finance	Active
Shaun	Walker SR	Sr. Field Inv. Coordinator	Active
Katie	Walko	Staff Regulatory Affairs Sp.	Active
Stuart	Wallace	Clinical Project Manager	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Windell	Wallace	Lead Field Inv. Coordinator	Active
Joe	Walsh	Inventory Control Specialist	Active
James	WALSH JR	Loaner Technician III	Active
Kathryn	Ward	Sr. Staff Qual. Eng., NC/CAPA	Active
Jeff	Webb	Sr. Sales Representative	Active
Zachary	Weglos	Sales Representative	Active
Jason	Weinrich	Sr. Spine Specialist	Active
Caroline	Weir	Program Mgr., Commercial Ops	Active
Stephen	Welkie	Sr. Sales Representative	Active
James	White	Sales Associate	Active
Matt	White	Sr. Sales Representative	Active
Joshua	Wholters	Commercial Ops Specialist	Active
Lauren	Wilch	Sr. Advanced Quality Engineer,	Active
Sean	wilinski	CNC Programmer/Machinist	Active
Ingrid	Wilkins	Manager, Field Inventory	Active
Brendan	Willard	Sr. Sales Representative	Active
Jon	Willard	Manager, Quality Assurance	Active
Jennifer	Wilson	Finance Associate, Invoicing	Active
Joan	Wilson	Sr. Sales Representative	Active
Kim	Winkler	Manager, HRBP	Active
Dustin	Winship	Sr. Sales Representative	Active
James	Wright	Commercial Ops Associate	Active
Kate	Wright	Bioskills Lab Assistant	Active
Max	Wright	Sr. Sales Representative	Active
Chase	Yearty	Sales Associate	Active
Emily	Young	Senior Lead Data Analyst	Active
Mike	Young	Regional Sales Manager	Active
Deann	Zamosky	Sr. Spine Specialist	Active
Mark	Zellers	Quality System Associate	Active
Noah	Zellers	Senior Data Engineer	Active
Loutie	Zerbo	Loaner Technician III	Active
Carolyn	Zineddin	PMS Coodinator	Active

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan		38-1239739
(State of incorporation)		(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan		49002
(Address of principal executive offices)		(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange
3.375% Notes due 2032	SYK32	New York Stock Exchange
3.625% Notes due 2036	SYK36	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $123,147,898,554 at June 30, 2024. There were 381,579,123 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2025 Annual Meeting of Shareholders (the 2025 proxy statement) are incorporated by reference into Part III.

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PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers,
we are driven
to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right	We do what we say	We grow talent	We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and artificial intelligence-assisted virtual care platform technology; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics and Spine, the Interventional Spine (IVS) portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. In addition, we changed the name of our "Orthopaedics and Spine" operating segment to "Orthopaedics."

Quarterly Net Sales - Enabling Technologies

	2024	2023	2022
Mar 31	$ 30	$ 31	$ 30
Jun 30	$ 31	$ 32	$ 25
Sep 30	$ 59	$ 54	$ 44
Dec 31	$ 32	$ 32	$ 32
Total	**$ 152**	**$ 149**	**$ 131**

Quarterly Net Sales - IVS

	2024	2023	2022
Mar 31	$ 98	$ 77	$ 65
Jun 30	$ 98	$ 83	$ 73
Sep 30	$ 117	$ 84	$ 72
Dec 31	$ 100	$ 83	$ 72
Total	**$ 413**	**$ 327**	**$ 282**

Quarterly Net Sales - Spinal Implants

	2024	2023	2022
Mar 31	$ 171	$ 176	$ 183
Jun 30	$ 178	$ 181	$ 193
Sep 30	$ 186	$ 180	$ 182
Dec 31	$ 172	$ 176	$ 175
Total	**$ 707**	**$ 713**	**$ 733**

Net Sales by Reportable Segment

	2024		2023		2022	
MedSurg and Neurotechnology	$ 13,518	60 %	$ 12,163	59 %	$ 10,893	59 %
Orthopaedics	9,077	40	8,335	41	7,556	41
Total	**$ 22,595**	**100 %**	**$ 20,498**	**100 %**	**$ 18,449**	**100 %**

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and artificial intelligence-assisted virtual care platform technology (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson MedTech (a subsidiary of Johnson & Johnson) and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson Medtech, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2024		2023		2022	
Instruments	$ 2,834	21 %	$ 2,534	21 %	$ 2,245	21 %
Endoscopy	3,389	25	3,068	25	2,759	25
Medical	3,852	28	3,459	28	3,031	28
Neurovascular	1,307	10	1,226	11	1,200	11
Neuro Cranial	2,136	16	1,876	15	1,658	15
Total	$ 13,518	100 %	$ 12,163	100 %	$ 10,893	100 %

In 2024 Instruments launched SurgiCount+ powered by Triton, which combines our existing sponge counting technology with artificial intelligence and quantifying blood loss software. We also launched CoPilot, which combines with our Spine Q guidance system to help surgeons plan and perform certain spinal procedures, including supporting bone resection, pedicle preparation and screw delivery.

In addition we completed the acquisition of Vertos Medical, Inc., a leader in interventional pain management solutions for chronic lower back pain caused by lumbar spinal stenosis. The acquisition of Vertos is complementary to our Interventional Spine business as we continue to focus on advanced pain procedures.

Endoscopy continued to deliver its 4K 1788 Camera platform to the market. Our 1788 Camera platform features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat and can be used to visualize indocyanine green and Cytalux.

Medical launched the LIFEPAK 35 monitor/defibrillator, our next generation platform designed to optimize care with new clinical features such as the new Glasgow 30.4 algorithm, cprINSIGHT, 15-lead monitoring capabilities, and STJ insight and mapping. LIFEPAK 35 combines a modern intuitive touch screen display and increased processing power with Bluetooth and WiFi data connectivity.

Medical also completed the acquisition of care.ai, a virtual care and ambient intelligence solutions platform. care.ai adds complementary technology that is expected to integrate seamlessly with the Vocera platform (Vocera) and Stryker's devices, providing customers with an enterprise-wide ecosystem that is intended to deliver dynamic clinical workflows and further the development of smart care facilities.

Neurovascular initiated a targeted launch of the Surpass Elite Flow Diverting Stent (FDS) in the U.S. and South Korea. Surpass Elite FDS is designed to reduce thrombin generation when compared to unmodified stents. Additionally, Neurovascular launched Surpass Evolve FDS in Japan. The Stryker FDS platform is designed to effectively treat aneurysms by redirecting blood flow away from the aneurysm to promote healing.

Orthopaedics

Orthopaedics products primarily include implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technologies, products and services they need to support each patient's clinical challenge.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, Johnson & Johnson MedTech and Smith & Nephew.

Composition of Orthopaedics Net Sales

	2024		2023		2022	
Knees	$ 2,447	27 %	$ 2,273	27 %	$ 1,997	26 %
Hips	1,704	19	1,544	18	1,413	19
Trauma and Extremities	3,507	39	3,147	38	2,807	37
Spinal Implants	707	8	713	9	733	10
Other	712	8	658	8	606	8
Total	$ 9,077	100 %	$ 8,335	100 %	$ 7,556	100 %

In 2024 we continued the full commercial launch of our Triathlon Hinge revision knee system. Triathlon Hinge received approval in August of 2023 and is now released in the U.S., Canada and New Zealand. We also continued delivering growth in total hip arthroplasty, particularly in the primary segment where Direct Anterior Reconstructive Technology and Mako Total Hip can help to reduce, if not eliminate, a surgeon's use of intraoperative fluoroscopy during direct anterior hip procedures. With the acquisition of SERF SAS, we strengthened distribution in key European markets and continue to scale differentiated solutions such as the Novae monolithic dual mobility cup engineered to deliver greater hip stability and reduce dislocation risk.

We continued to expand our global footprint of Mako SmartRobotics™ in 2024 which is now sold in more than 45 countries. To date more than one million robotic Mako Total Knees and 1.5 million robotic procedures across Total Hips, Total Knees and Partial Knees have been performed globally. Stryker's Joint Replacement division also launched the "Scan. Plan. Mako Can." direct to patient campaign, accelerating awareness of Mako technology in the U.S.

Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

In December 2024 we performed our first Mako Shoulder procedure using robotic-arm assistance to remove bone, prepare the glenoid surface and enable positioning and placement of the Perform Reversed Glenoid implant.

In 2024 Trauma launched Pangea, a comprehensive variable angle plating portfolio designed to optimize plate fit to bone utilizing simple, intuitive instrumentation that enhances ease of use and reproducibility. These combined solutions empower Stryker to deliver a complete portfolio across all trauma segments.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2024 we owned approximately 5,600 United States patents and approximately 8,600 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the

summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2022, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. Any resulting investigations and prosecutions potentially carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2024 we had approximately 53,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups, which are open to all employees, to focus on creating community and belonging

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer to our executive officers.

Information about our Executive Officers

As of January 31, 2025

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	59	Chair, Chief Executive Officer and President	2011
Yin C. Becker	61	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	59	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	63	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	55	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	54	Vice President, Chief Legal Officer	2019
Viju S. Menon	57	Group President, Global Quality and Operations	2018
J. Andrew Pierce	51	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	48	Group President, Orthopaedics	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2025 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our or Inari Medical, Inc.'s ("Inari") products;
- geopolitical risks, including from international conflicts, which could, among other things, lead to increased market volatility;

- pricing pressures generally, including cost-containment measures that have adversely affected and could in the future adversely affect the price of or demand for our or Inari's products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products, including Inari products, by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in coverage and reimbursement levels from third-party payors;
- changes in the competitive environment;
- breaches, failures or other disruptions of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes, including our acquisition of Inari;
- our ability to realize any anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- uncertainties as to the timing of the tender offer for shares of Inari common stock and the subsequent merger with Inari;
- uncertainties as to how many of Inari's stockholders will tender their shares in the tender offer;
- the failure to satisfy any of the closing conditions to the acquisition of Inari, including the expiration or termination of the Hart-Scott-Rodino Antitrust Improvements Act waiting period (and the risk that such governmental approval may result in the imposition of conditions that could adversely affect the expected benefits of the transaction);
- delays in consummating the acquisition of Inari or the risk that the transaction may not close at all;
- unexpected liabilities, costs, charges or expenses in connection with the acquisition of Inari;
- the effects of the proposed Inari transaction (or the announcement thereof) on the parties' relationships with employees, customers, other business partners or governmental entities; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to the risk of product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to any raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to, among other things, the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, business disruptions, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer, possibly materially. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, in recent years, the market has experienced inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may in the future result in, high interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may in the future experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, high interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors, including changes in reimbursement practices and coverage policies and third-party payor cost containment measures: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in coverage or reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. Coverage policies and reimbursement levels can vary across the payer community globally, regionally, and locally, and may affect which products customers purchase, the market acceptance rate for new technologies and the prices customers are willing to pay for those products in a particular jurisdiction. Furthermore, any changes to the coverage or reimbursement landscape, or adverse decisions relating to our products by administrators of these systems could significantly reduce reimbursement for procedures using our products or result in denial of reimbursement for those products, which could adversely affect customer demand, or the price customers are willing to pay for such products. Public and private payers have challenged, and are expected to continue to challenge, prices charged for medical products and services. Such downward pricing pressures from any or all of these payers may result in an adverse effect on our business, results of operations, financial condition and cash flows. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition and the regulatory burden in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation, new product development and improvement of existing products. New business models, products and surgical procedures, as well as improvements to existing products, are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, including by our existing competitors and new market entrants, which could adversely impact demand for certain of our existing products. The success of our products and services depends on, among other things, our ability to properly identify customer needs and predict future needs; innovate and develop new technologies, services and applications at an accelerated pace; and appropriately allocate our research and development spending to products and services with higher growth. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We work with healthcare professionals in a transparent and responsible manner and seek to maintain these relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in coverage or reimbursement levels from third-party payors in the United States and other countries; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with

the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability and uncertainty; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which has increased the risks we are subject to.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Furthermore, numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Emerging technologies such as generative artificial intelligence (AI) may be used by malicious actors to create more targeted phishing narratives, spread disinformation about us or our products or otherwise strengthen social engineering capabilities. Some of our products, services, and information technology systems contain or use open-source software which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, unauthorized access to, and disruptions of, products or systems. While such breaches, unauthorized access and disruptions have not had a material effect on us to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity or other technology related incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment and customer requirements related to information security, data collection and use, and privacy become increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability.

Hardware and software failures or delays in our key information technology systems, networks, processes or sites could disrupt our operations, cause the loss of confidential information or otherwise adversely impact our business. Our systems, networks, processes and sites may be vulnerable to damage, disruptions and shutdown from a variety of sources, including malfunctions in maintenance updates or security patches, design defects, the age of the technology, network failures, modernization or other initiatives, human acts and natural disasters. For example, some of our information technology systems contain legacy third-party software components for which we depend on a layered security

approach to protect against exploitation, which may not be effective. Any such damage or disruptions could also compromise the security of our information systems and networks. These issues can also arise as a result of failures by, or in the software or hardware of, third parties, including networks or service providers, with whom we do business and over whom we have limited or no control. Any disruption or failure of our systems, networks, processes or sites could have a material impact on our business and operations.

If our IT systems, networks or processes are damaged or cease to function properly for any reason, the networks, service providers, hardware or software we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive workforce in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by

governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. It is not possible to predict whether elective medical procedures will be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and may continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm, among other things.

Our use of AI and other emerging technologies could adversely impact our business and financial results: We have begun to deploy AI and other emerging technologies in various facets of our operations and we continue to explore further use cases. The rapid advancement of these technologies presents opportunities for us in research, manufacturing, commercialization, and other business endeavors, but also entails risks, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. In addition, any disruption or failure in the AI functionality we incorporate into our business activities, products or services could adversely impact our business or result in delays or errors in our product offerings. The legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity and privacy and data protection. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant costs on us and limit our ability to effectively develop, deploy or use AI technologies. Furthermore, if we are unable to effectively manage the use of AI technologies by our employees and service providers, our confidential information, intellectual property and reputation could be put at risk. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with prior pandemics, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks that revise the existing profit allocation and nexus rules (Pillar 1) and ensure a minimal level of taxation (Pillar 2), respectively. In 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws are effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes, could increase tax expense in future periods.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to healthcare or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. Both in the U.S. and internationally, governmental authorities may make legislative or administrative reforms to existing reimbursement programs, make adverse decisions relating to our

products' coverage or reimbursement, or make changes to patient access to healthcare, all of which could adversely impact the demand for and usage of our products or the prices that our customers are willing to pay for them. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. For example, governmental authorities in the United States and internationally have or are considering adopting regulations on the use of per- and polyfluoroalkyl substances. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We may also be subject to legal obligations in some countries that require disclosure or sharing of proprietary information. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws have in the past resulted and could in the future result in investigations, litigation or government proceedings, and we have been and may in the future be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. For example, in 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and enforcement and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial

Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive) mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The European Product Liability Directive was revised in 2024 and will become fully adopted into each member state's national laws by 2026. The revised Product Liability Directive and Collective Redress Directive exposes us to additional litigation risks and could result in significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on intellectual proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents and the expiration of patents may lead to a loss of exclusive rights and/or increased competition.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties, financing transactions in currencies other than the United States Dollar and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars. In recent years, currency exchange rates have been especially volatile, and these currency fluctuations have affected, and may continue to affect, our results of operations.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve, including in diverging directions. On occasion, we announce new initiatives and make disclosures, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest and applicable regulatory requirements, which include environment and sustainability, workforce-related issues, diversity, equity and inclusion and supply chain management, among others. Implementation of these initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in, among other things, reduced demand for our products, reduced profits, increased investigations and litigation and an increased risk of reputational damage. If we are unable to satisfy evolving criteria, certain investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate or undesirable. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change have increased and are expected to further increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures and flooding, which could cause more significant business and supply chain

interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors periodically. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 27 company-owned and 297 leased locations worldwide including 45 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products.

We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various ongoing proceedings, legal actions and claims arising in the normal course of our business, including proceedings related to product, labor, intellectual property and other matters. Refer to Note 7 to our Consolidated Financial Statements for further information.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2025 there were 2,510 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2024 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2024 was $1,033.

In the fourth quarter 2024 we did not issue shares of our common stock as performance incentive awards to employees. When issued, these shares are not registered under the Securities Act of 1933 based on the conclusion that the awards are not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2019 in our common stock and each of the indices.



Company / Index	2019	2020	2021	2022	2023	2024
Stryker Corporation	**$ 100.00**	**$ 118.17**	**$ 130.25**	**$ 120.59**	**$ 149.29**	**$ 181.15**
S&P 500 Index	$ 100.00	$ 118.40	$ 152.39	$ 124.79	$ 157.59	$ 197.02
S&P 500 Health Care Index	$ 100.00	$ 113.45	$ 143.09	$ 140.29	$ 143.18	$ 146.87

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2024	2023	2022	2021	2020
Net sales	**$ 22,595**	**$ 20,498**	**$ 18,449**	**$ 17,108**	**$ 14,351**
Cost of sales	8,155	7,440	6,871	6,140	5,294
Gross profit	**$ 14,440**	**$ 13,058**	**$ 11,578**	**$ 10,968**	**$ 9,057**
Research, development and engineering expenses	1,466	1,388	1,454	1,235	984
Selling, general and administrative expenses	7,685	7,111	6,386	6,266	5,163
Amortization of intangible assets	623	635	627	619	472
Goodwill and other impairments	977	36	270	264	215
Total operating expenses	$ 10,751	$ 9,170	$ 8,737	$ 8,384	$ 6,834
Operating income	**$ 3,689**	**$ 3,888**	**$ 2,841**	**$ 2,584**	**$ 2,223**
Other income (expense), net	(197)	(215)	(158)	(303)	(269)
Earnings before income taxes	**$ 3,492**	**$ 3,673**	**$ 2,683**	**$ 2,281**	**$ 1,954**
Income taxes	499	508	325	287	355
Net earnings	**$ 2,993**	**$ 3,165**	**$ 2,358**	**$ 1,994**	**$ 1,599**
Net earnings per share of common stock:					
Basic	$ 7.86	$ 8.34	$ 6.23	$ 5.29	$ 4.26
Diluted	$ 7.76	$ 8.25	$ 6.17	$ 5.21	$ 4.20
Dividends declared per share of common stock	**$ 3.240**	**$ 3.050**	**$ 2.835**	**$ 2.585**	**$ 2.355**
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,743	$ 3,053	$ 1,928	$ 3,019	$ 3,024
Accounts receivable, net	3,987	3,765	3,565	3,022	2,701
Inventories	4,774	4,843	3,995	3,314	3,494
Property, plant and equipment, net	3,448	3,215	2,970	2,833	2,752
Total assets	**$ 42,971**	**$ 39,912**	**$ 36,884**	**$ 34,631**	**$ 34,330**
Accounts payable	1,679	1,517	1,413	1,129	810
Total debt	13,597	12,995	13,048	12,479	13,991
Shareholders' equity	**$ 20,634**	**$ 18,593**	**$ 16,616**	**$ 14,877**	**$ 13,084**
Cash Flow Data					
Net cash provided by operating activities	**$ 4,242**	**$ 3,711**	**$ 2,624**	**$ 3,263**	**$ 3,277**
Purchases of property, plant and equipment	755	575	588	525	487
Depreciation	427	393	371	371	340
Acquisitions, net of cash acquired	1,628	390	2,563	339	4,222
Amortization of intangible assets	623	635	627	619	472
Payments of dividends	1,219	1,139	1,051	950	863
Repurchase of common stock	—	—	—	—	—
Other Data					
Number of shareholders of record	2,520	2,518	2,533	2,551	2,597
Approximate number of employees	53,000	52,000	51,000	46,000	43,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Overview of 2024

In 2024 we achieved reported net sales growth of 10.2%. Excluding the impact of acquisitions and divestitures, sales grew 10.2% in constant currency. We reported net earnings of $2,993 and net earnings per diluted share of $7.76. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,700 and adjusted net earnings per diluted share[1] of $12.19 representing growth of 15.0%.

We continued our capital allocation strategy by investing $1,628 in acquisitions and paying $1,219 in dividends to our shareholders.

In 2024 we completed various acquisitions for total consideration of $1,628 in upfront payments, net of cash acquired, as well as $400 of contingent consideration if certain commercial or clinical milestones are achieved. Refer to Note 6 to our Consolidated Financial Statements for further information.

In May 2024 we repaid the outstanding $600 principal amount of the 3.375% senior unsecured notes due May 15, 2024. In September 2024 we issued $750 of 4.250% senior unsecured notes due September 11, 2029, €800 of 3.375% senior unsecured notes due September 11, 2032, $750 of 4.625% senior unsecured notes due September 11, 2034 and €600 of 3.625% senior unsecured notes due September 11, 2036. In November 2024 we repaid the outstanding €500 of floating rate senior notes and in December 2024 we repaid €850 of 0.250% senior unsecured notes.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2024	2023	2022	2024	2023	2022	2024 vs. 2023	2023 vs. 2022
Net sales	$ 22,595	$ 20,498	$ 18,449	100.0 %	100.0 %	100.0 %	10.2 %	11.1 %
Gross profit	14,440	13,058	11,578	63.9	63.7	62.8	10.6	12.8
Research, development and engineering expenses	1,466	1,388	1,454	6.5	6.8	7.9	5.6	(4.5)
Selling, general and administrative expenses	7,685	7,111	6,386	34.0	34.7	34.6	8.1	11.4
Amortization of intangible assets	623	635	627	2.8	3.1	3.4	(1.9)	1.3
Goodwill and other impairments	977	36	270	4.3	0.2	1.5	nm	nm
Other income (expense), net	(197)	(215)	(158)	(0.9)	(1.0)	(0.9)	(8.4)	36.1
Income taxes	499	508	325	nm	nm	nm	(1.8)	56.3
Net earnings	$ 2,993	$ 3,165	$ 2,358	13.2 %	15.4 %	12.8 %	(5.4)%	34.2 %
Net earnings per diluted share	$ 7.76	$ 8.25	$ 6.17				(5.9)%	33.7 %
Adjusted net earnings per diluted share[1]	$ 12.19	$ 10.60	$ 9.34				15.0 %	13.5 %

nm - not meaningful

Geographic and Segment Net Sales

				Percentage Change			
				2024 vs. 2023		2023 vs. 2022	
	2024	2023	2022	As Reported	Constant Currency	As Reported	Constant Currency
Geographic:							
United States	$ 16,943	$ 15,257	$ 13,638	11.0 %	11.0 %	11.9 %	11.9 %
International	5,652	5,241	4,811	7.9	9.8	8.9	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %
Segment:							
MedSurg and Neurotechnology	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	11.7 %	12.2 %
Orthopaedics	9,077	8,335	7,556	8.9	9.4	10.3	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %

Dollar amounts in millions except per share amounts or as otherwise specified.

Supplemental Net Sales Growth Information

				Percentage Change									
				2024 vs. 2023					2023 vs. 2022				
						United States	International				United States	International	
	2024	2023	2022	As Reported	Constant Currency	As Reported	As Reported	Constant Currency	As Reported	Constant Currency	As Reported	As Reported	Constant Currency
MedSurg and Neurotechnology:													
Instruments	$ 2,834	$ 2,534	$ 2,245	11.9 %	12.1 %	12.5 %	9.5 %	10.6 %	12.9 %	13.0 %	13.5 %	10.4 %	11.8 %
Endoscopy	3,389	3,068	2,759	10.5	11.0	11.1	7.7	10.7	11.2	11.7	11.9	8.0	9.9
Medical	3,852	3,459	3,031	11.4	11.7	14.6	(2.0)	(0.3)	14.1	14.4	15.0	10.7	12.3
Neurovascular	1,307	1,226	1,200	6.6	8.2	4.7	7.9	10.5	2.2	4.0	8.3	(1.5)	1.5
Neuro Cranial	2,136	1,876	1,658	13.9	14.1	15.0	8.7	10.2	13.1	13.4	12.7	15.4	16.8
	$ 13,518	**$ 12,163**	**$ 10,893**	**11.1 %**	**11.6 %**	**12.7 %**	**5.9 %**	**7.9 %**	**11.7 %**	**12.2 %**	**13.1 %**	**7.2 %**	**9.2 %**
Orthopaedics:													
Knees	$ 2,447	$ 2,273	$ 1,997	7.6 %	8.2 %	6.7 %	10.4 %	12.2 %	13.8 %	14.4 %	12.3 %	18.5 %	20.9 %
Hips	1,704	1,544	1,413	10.3	11.3	7.2	15.9	18.4	9.3	10.4	10.3	7.5	10.7
Trauma and Extremities	3,507	3,147	2,807	11.4	11.6	12.6	8.3	9.1	12.1	12.2	12.9	10.1	10.5
Spinal Implants	707	713	733	(0.7)	(0.3)	(2.1)	2.5	3.8	(2.7)	(2.0)	(2.2)	(4.1)	(3.4)
Other	712	658	606	8.1	9.6	7.3	10.1	15.4	8.6	9.5	2.9	25.8	32.3
	$ 9,077	**$ 8,335**	**$ 7,556**	**8.9 %**	**9.4 %**	**8.4 %**	**10.2 %**	**12.0 %**	**10.3 %**	**10.9 %**	**10.0 %**	**11.1 %**	**13.1 %**
Total	**$ 22,595**	**$ 20,498**	**$ 18,449**	**10.2 %**	**10.7 %**	**11.0 %**	**7.9 %**	**9.8 %**	**11.1 %**	**11.6 %**	**11.9 %**	**8.9 %**	**10.9 %**

Note: In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics, the interventional spine portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. Neuro Cranial includes sales related to interventional spine of $413, $327 and $282 for 2024, 2023 and 2022. Other Orthopaedics includes sales related to Enabling Technologies of $152, $149 and $131 for 2024, 2023 and 2022. In the first quarter 2024 a product line previously included in Instruments has been reclassified to Endoscopy to align with a change in our internal reporting structure. We have reflected these changes in all historical periods presented.

Consolidated Net Sales

Consolidated net sales in 2024 increased 10.2% as reported and 10.7% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.5% impact of acquisitions and divestitures, net sales in constant currency increased by 9.1% from increased unit volume and 1.1% due to higher prices. The unit volume increase was primarily due to higher shipments across all businesses.

Consolidated net sales in 2023 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 10.9% from increased unit volume and 0.6% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses and most Orthopaedics businesses.

MedSurg and Neurotechnology Net Sales

MedSurg and Neurotechnology net sales in 2024 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.4% impact of acquisitions and divestitures, net sales in constant currency increased by 9.5% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

MedSurg and Neurotechnology net sales in 2023 increased 11.7% as reported and 12.2% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.3% impact of acquisitions and divestitures, net sales in constant currency increased by 10.2% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

Orthopaedics Net Sales

Orthopaedics net sales in 2024 increased 8.9% as reported and 9.4% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.7% impact of acquisitions and divestitures, net sales in constant currency increased by 8.7% from increased unit volume. The unit volume increase was due to higher shipments across all Orthopaedics businesses.

Orthopaedics net sales in 2023 increased 10.3% as reported and 10.9% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.6%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 11.9% from increased unit volume partially offset by 1.1% due to lower prices. The unit volume increase was due to higher shipments across most Orthopaedics businesses.

Gross Profit

Gross profit was $14,440, $13,058 and $11,578 in 2024, 2023, and 2022. The key components of the change were:

	Gross Profit Percent Net Sales
2022	**62.8 %**
Sales pricing	20 bps
Volume and mix	100 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	10 bps
2023	**63.7 %**
Sales pricing	40 bps
Volume and mix	60 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	(20) bps
Structural optimization and other special charges	(20) bps
2024	**63.9 %**

Gross profit as a percentage of net sales increased to 63.9% in 2024 from 63.7% in 2023 due to higher sales pricing and favorable volume partially offset by higher manufacturing and supply chain costs primarily due to inflationary pressures impacting fixed and variable manufacturing costs as well as higher amortization of inventory stepped up to fair value.

Gross profit as a percentage of net sales increased to 63.7% in 2023 from 62.8% in 2022 due to higher sales pricing and favorable volume offset by higher manufacturing and supply chain costs primarily due to higher raw material costs in the first six months of 2023 and supply chain inefficiencies.

While segment mix was not a significant driver of the change in gross profit as a percent of net sales between 2024, 2023 and 2022, we generally expect segment mix to have an unfavorable impact for the foreseeable future as we anticipate more rapid sales growth in our lower gross margin MedSurg and Neurotechnology segment than our Orthopaedics segment.

Research, Development and Engineering Expenses

Research, development and engineering expenses as a percentage of net sales in 2024 decreased to 6.5% from 6.8% in 2023 primarily due to lower spend on medical device regulations in the European Union.

Research, development and engineering expenses as a percentage of net sales in 2023 decreased to 6.8% from 7.9% in 2022 primarily due to increased spending for product launches, the write-off of certain intangible assets and higher spend related to the new medical device regulations in the European Union in 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses as a percentage of net sales in 2024 decreased to 34.0% from 34.7% in 2023 primarily due to continued spend discipline and lower charges for structural optimization and certain legal matters partially offset by higher acquisition-related costs.

Selling, general and administrative expenses as a percentage of net sales in 2023 of 34.7% remained relatively flat with 34.6% in 2022 as charges of $132 related to share-based awards for Vocera employees that vested upon our acquisition in 2022 were partially offset by disciplined increases in spend and investments in 2023 to support our growth, including sales growth incentives and increased spend on travel and meetings. In addition, in 2022 we determined that certain commercial and regulatory milestones related to technology acquired in the purchase of Mobius Imaging and Cardan Robotics were no longer probable of being achieved and recorded $110 to reduce the fair value of contingent consideration.

Amortization of Intangible Assets

Amortization of intangible assets was $623, $635 and $627 in 2024, 2023 and 2022. These amounts include amortization related to intangible assets acquired in 2024 from various acquisitions, 2023 from Cerus Endovascular Limited (Cerus) and 2022 from Vocera. Refer to Notes 6 and 8 to our Consolidated Financial Statements for further information.

Goodwill and Other Impairments

In 2024 and 2022 we recorded goodwill impairment charges of $456 and $216 related to our Spine business.

In 2024 we recognized an estimated loss of $362 as a result of classifying certain assets in our Spinal Implants business as held for sale. Refer to Notes 8, 16 and 17 to our Consolidated Financial Statements for further information.

In 2024, 2023 and 2022 we recorded other impairments of $159, $36 and $54. Refer to Notes 15 and 16 to our Consolidated Financial Statements for further information.

Operating Income

Operating income was $3,689, $3,888 and $2,841 in 2024, 2023 and 2022. Operating income decreased as a percentage of sales to 16.3% in 2024 from 19.0% in 2023 and increased from 15.4% in 2022. Refer to the comments above for discussion of the primary drivers of the change.

MedSurg and Neurotechnology operating income as a percentage of net sales increased to 29.6% in 2024 from 28.5% in 2023. MedSurg and Neurotechnology operating income as a percentage of net sales increased to 28.5% in 2023 from 26.0% in 2022. Orthopaedics operating income as a percentage of net sales increased to 28.5% in 2024 from 27.2% in 2023. Orthopaedics operating income as a percentage of net sales increased to 27.2% in 2023 from 29.1% in 2022. The key components of the change were:

	Operating Income Percent Net Sales	
	MedSurg and Neurotechnology	Orthopaedics
2022	**26.0 %**	**29.1 %**
Sales pricing	70 bps	(30) bps
Volume	100 bps	80 bps
Manufacturing and supply chain costs	90 bps	(220) bps
Research, development and engineering expenses	50 bps	20 bps
Selling, general and administrative expenses	(60) bps	(40) bps
2023	**28.5 %**	**27.2 %**
Sales pricing	70 bps	0 bps
Volume	40 bps	70 bps
Manufacturing and supply chain costs	(40) bps	(20) bps
Research, development and engineering expenses	0 bps	10 bps
Selling, general and administrative expenses	40 bps	70 bps
2024	**29.6 %**	**28.5 %**

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2024 from 2023 was primarily driven by higher unit volumes, higher prices and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2023 from 2022 was primarily driven by higher unit volumes, higher prices and lower manufacturing and supply chain costs due to supply chain challenges impacting capital products in our MedSurg businesses in 2022 which improved in 2023 partially offset by higher selling, general and administrative expenses as a percentage of sales due to continued investments including sales growth incentives and a more normalized cadence of travel and meetings.

The increase in Orthopaedics operating income as a percentage of net sales for 2024 from 2023 was primarily driven by higher sales volumes and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The decrease in Orthopaedics operating income as a percentage of net sales for 2023 from 2022 was primarily driven by higher higher manufacturing and supply chain costs primarily due to increased inventory reserves partially offset by higher unit volumes.

Other Income (Expense), Net

Other income (expense), net was ($197), ($215) and ($158) in 2024, 2023 and 2022. The decrease in net expense in 2024 from 2023 was primarily due to higher interest income partially offset by lower interest expense in 2024. The increase in net expense in 2023 from 2022 was primarily due to the release of accrued interest of $50 in 2022 related to the effective settlement of the United States federal income tax audit for years 2014 through 2018. Refer to Note 11 to our Consolidated Financial Statements for further information and higher interest income in 2023.

Income Taxes

Our effective tax rate was 14.3%, 13.8% and 12.1% for 2024, 2023 and 2022. The effective income tax rate for 2024 decreased from 2023 due to the 2024 deferred tax benefit on the outside basis difference related to the anticipated sale of the Spinal Implants business partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. The effective income tax rate for 2023 increased from 2022 due to the 2022 effective settlement of the United States federal income tax audit for years 2014 through 2018 and the 2022 reversal of deferred income tax on undistributed earnings of foreign subsidiaries partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. Additionally, the effective income tax rates for 2024, 2023 and 2022 reflect the continued lower effective income tax rates as a result of our European operations and certain discrete tax items.

The Organisation for Economic Cooperation and Development (OECD), which represents a coalition of member countries, has put forth two proposed base erosion and profit shifting frameworks that revise the existing profit allocation and nexus rules (Pillar One) and ensure a minimal level of taxation (Pillar Two). On December 12, 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws became effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes could increase tax expense in future periods.

Net Earnings

Net earnings for 2024 increased to $2,993 or $7.76 per diluted share from $3,165 or $8.25 per diluted share in 2023 and $2,358 or $6.17 per diluted share in 2022. Refer to the comments above for discussion of the primary drivers of the change.

Non-GAAP Financial Measures

We supplement the reporting of our financial information determined under accounting principles generally accepted in the United States (GAAP) with certain non-GAAP financial measures, including percentage sales growth in constant currency; percentage organic sales growth; adjusted gross profit; adjusted selling, general and administrative expenses; adjusted research, development and engineering expenses; adjusted operating income; adjusted other income (expense), net; adjusted income taxes; adjusted effective income tax rate; adjusted net earnings; and adjusted net earnings per diluted share (Diluted EPS). We believe these non-GAAP financial measures provide meaningful information to assist investors and shareholders in understanding our financial results and assessing our prospects for future performance. Management believes percentage sales growth in constant currency and the other adjusted measures described above are important indicators of our operations because they exclude items that may not be indicative of or are unrelated to our core operating results and provide a baseline for analyzing trends in our underlying businesses. Management uses these non-GAAP financial measures for reviewing the operating results of reportable business segments and analyzing potential future business trends in connection with our budget process and bases certain management incentive compensation on these non-GAAP financial measures. To measure percentage sales growth in constant currency, we remove the impact of changes in foreign currency exchange rates that affect the comparability and trend of sales. Percentage sales growth in constant currency is calculated by translating current and prior year results at the same foreign currency exchange rate. To measure percentage organic sales growth, we remove the impact of changes in foreign currency exchange rates, acquisitions and divestitures, which affect the comparability and trend of sales. Percentage organic sales growth is calculated by translating current year and prior year results at the same foreign currency exchange rates excluding the impact of acquisitions and divestitures. To measure earnings performance on a consistent and comparable basis, we exclude certain items that affect the comparability of operating results and the trend of earnings. The income tax effect of each adjustment was determined based on the tax effect of the jurisdiction in which the related pre-tax adjustment was recorded. These adjustments are irregular in timing and may not be indicative of our past and future performance. The following are examples of the types of adjustments that may be included in a period:

1. *Acquisition and integration-related costs.* Costs related to integrating recently acquired businesses (e.g., costs associated with the termination of sales relationships, employee retention and workforce reductions, manufacturing integration costs and other integration-related activities), changes in the fair value of contingent consideration, amortization of inventory stepped-up to fair value, specific costs (e.g., deal costs and costs associated with legal entity rationalization) related to the consummation of the acquisition process and legal entity rationalization and acquisition-related tax items.
2. *Amortization of purchased intangible assets.* Periodic amortization expense related to purchased intangible assets.
3. *Structural optimization and other special charges.* Costs associated with employee retention and workforce reductions, the closure or transfer of manufacturing and other facilities (e.g., site closure costs, contract termination costs and redundant employee costs during the work transfers), product line exits (primarily inventory, long-lived asset and specifically-identified intangible asset write-offs), certain long-lived and intangible asset write-offs and impairments and other charges.
4. *Medical device regulations.* Costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the new medical device reporting regulations and other requirements of the European Union.
5. *Recall-related matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve the Rejuvenate, LFIT V40, Wright legacy hip products and other product recalls.
6. *Regulatory and legal matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters

and the amount of favorable awards from settlements.

7. *Tax matters*. Impact of accounting for certain significant and discrete tax items.

Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names. These adjusted financial measures should not be considered in isolation or as a substitute for reported sales growth, gross profit, selling, general and administrative expenses, research, development and engineering expenses, operating income, other income (expense), net, income taxes, effective income tax rate, net earnings and net earnings per diluted share, the most directly comparable GAAP financial measures. These non-GAAP financial measures are an additional way of viewing aspects of our operations when viewed with our GAAP results and the reconciliations to corresponding GAAP financial measures at the end of the discussion of Consolidated Results of Operations below. We strongly encourage investors and shareholders to review our financial statements and publicly-filed reports in their entirety and not to rely on any single financial measure.

The weighted-average diluted shares outstanding used in the calculation of adjusted net earnings per diluted share are the same as those used in the calculation of reported net earnings per diluted share for the respective period.

Reconciliation of the Most Directly Comparable GAAP Financial Measure to Non-GAAP Financial Measure

2024	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 14,440	$ 7,685	$ 1,466	$ 3,689	$ (197)	$ 499	$ 2,993	14.3 %	$ 7.76
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	46	—	—	46	—	12	34	0.2	0.09
Other acquisition and integration-related (a)	—	(107)	(1)	108	—	23	85	0.2	0.22
Amortization of purchased intangible assets	—	—	—	623	—	128	495	1.0	1.28
Structural optimization and other special charges (b)	59	(77)	(2)	138	1	29	110	0.3	0.29
Goodwill and other impairments (c)	—	—	—	977	—	125	852	(0.6)	2.21
Medical device regulations (d)	9	—	(49)	58	—	14	44	0.1	0.11
Recall-related matters (e)	11	(29)	—	40	—	10	30	0.1	0.08
Regulatory and legal matters (f)	—	(36)	—	36	—	7	29	0.1	0.08
Tax matters (g)	—	—	—	—	—	(28)	28	(0.9)	0.07
Adjusted	$ 14,565	$ 7,436	$ 1,414	$ 5,715	$ (196)	$ 819	$ 4,700	14.8 %	$ 12.19

2023	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 13,058	$ 7,111	$ 1,388	$ 3,888	$ (215)	$ 508	$ 3,165	13.8 %	$ 8.25
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	—	—	—	—	—	—	—	—	—
Other acquisition and integration-related (a)	—	(20)	—	20	—	(25)	45	(0.8)	0.12
Amortization of purchased intangible assets	—	—	—	635	—	132	503	1.2	1.31
Structural optimization and other special charges (b)	39	(130)	(1)	170	—	38	132	0.4	0.34
Goodwill and other impairments (c)	—	—	—	36	—	9	27	0.1	0.08
Medical device regulations (d)	2	—	(94)	96	—	22	74	0.2	0.19
Recall-related matters (e)	—	(18)	—	18	—	4	14	—	0.04
Regulatory and legal matters (f)	—	(92)	—	92	—	29	63	0.4	0.16
Tax matters (g)	—	—	—	—	(8)	(51)	43	(1.2)	0.11
Adjusted	$ 13,099	$ 6,851	$ 1,293	$ 4,955	$ (223)	$ 666	$ 4,066	14.1 %	$ 10.60

2022	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 11,578	$ 6,386	$ 1,454	$ 2,841	$ (158)	$ 325	$ 2,358	12.1 %	$ 6.17
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	12	—	—	12	—	3	9	—	0.02
Other acquisition and integration-related (a)	—	(138)	—	138	—	34	104	0.6	0.27
Amortization of purchased intangible assets	—	—	—	627	—	132	495	1.7	1.30
Structural optimization and other special charges (b)	56	(152)	(87)	295	—	61	234	0.8	0.61
Goodwill and other impairments (c)	—	—	—	270	—	5	265	(1.2)	0.70
Medical device regulations (d)	3	—	(137)	140	—	25	115	0.2	0.30
Recall-related matters (e)	—	15	—	(15)	—	(3)	(12)	—	(0.03)
Regulatory and legal matters (f)	—	(76)	—	76	—	7	69	(0.2)	0.18
Tax matters (g)	—	—	—	—	(75)	(9)	(66)	0.1	(0.18)
Adjusted	$ 11,649	$ 6,035	$ 1,230	$ 4,384	$ (233)	$ 580	$ 3,571	14.1 %	$ 9.34

(a) Charges represent certain acquisition and integration-related costs associated with acquisitions, including:

	2024	2023	2022
Termination of sales relationships	$ 4	$ 5	$ 21
Employee retention and workforce reductions	22	6	33
Changes in the fair value of contingent consideration	8	(1)	(135)
Manufacturing integration costs	3	2	32
Stock compensation payments upon a change in control	22	—	132
Other integration-related activities	49	8	55
Adjustments to Operating Income	**$ 108**	**$ 20**	**$ 138**
Charges for acquisition-related tax provisions	—	—	—
Other income taxes related to acquisition and integration-related costs	23	(25)	34
Adjustments to Income Taxes	**$ 23**	**$ (25)**	**$ 34**
Adjustments to Net Earnings	**$ 85**	**$ 45**	**$ 104**

(b) Structural optimization and other special charges represent the costs associated with:

	2024	2023	2022
Employee retention and workforce reductions	$ 23	$ 69	$ 74
Closure/transfer of manufacturing and other facilities	31	50	83
Product line exits	37	22	34
Termination of sales relationships	8	—	—
Other charges	39	29	104
Adjustments to Operating Income	**$ 138**	**$ 170**	**$ 295**
Adjustments to Other Income (Expense), Net	**$ 1**	**$ —**	**$ —**
Adjustments to Income Taxes	**$ 29**	**$ 38**	**$ 61**
Adjustments to Net Earnings	**$ 110**	**$ 132**	**$ 234**

(c) Goodwill and other impairments represent the costs associated with:

	2024	2023	2022
Goodwill impairments	$ 456	$ —	$ 216
Certain long-lived and intangible asset write-offs and impairments	466	26	8
Product line exits (e.g., long-lived asset and specifically-identified intangible asset write-offs)	55	10	46
Adjustments to Operating Income	**$ 977**	**$ 36**	**$ 270**
Adjustments to Income Taxes	**$ 125**	**$ 9**	**$ 5**
Adjustments to Net Earnings	**$ 852**	**$ 27**	**$ 265**

(d) Charges represent the costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the medical device reporting regulations and other requirements of the new medical device regulations in the European Union.

(e) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain recall-related matters.

(f) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters and the amount of favorable awards from settlements.

(g) Benefits / (charges) represent the accounting impact of certain significant and discrete tax items, including:

	2024	2023	2022
Adjustments related to the transfer of certain intellectual properties between tax jurisdictions	$ (185)	$ (89)	$ (182)
Certain tax audit settlements	(1)	24	162
Reversal of deferred income tax on undistributed earnings of foreign subsidiaries	—	—	71
Deferred tax benefit on outside basis related to the anticipated sale of the Spinal Implants business	170	—	—
Other significant and discrete tax items	(12)	14	(60)
Adjustments to Income Taxes	**$ (28)**	**$ (51)**	**$ (9)**
Benefits for certain tax audit settlements	—	(9)	(45)
Other tax related adjustments	—	1	(30)
Adjustments to Other Income (Expense), Net	**$ —**	**$ (8)**	**$ (75)**
Adjustments to Net Earnings	**$ 28**	**$ 43**	**$ (66)**

FINANCIAL CONDITION AND LIQUIDITY

Net cash provided by (used in):	2024	2023	2022
Operating activities	$ 4,242	$ 3,711	$ 2,624
Investing activities	(3,000)	(962)	(2,924)
Financing activities	(525)	(1,594)	(749)
Effect of exchange rate changes	(36)	(28)	(51)
Change in cash and cash equivalents	**$ 681**	**$ 1,127**	**$ (1,100)**

We believe our financial condition continues to be of high quality, as evidenced by our ability to generate substantial cash from operations and to readily access capital markets at competitive rates despite the current macroeconomic environment. Operating cash flow provides the primary source of cash to fund operating needs and capital expenditures. Excess operating cash is used first to fund acquisitions to complement our portfolio of businesses. Other discretionary uses include dividends and share repurchases. We supplement operating cash flow with debt to fund our activities as necessary. Our overall cash position reflects our business results and a global cash management strategy that takes into account liquidity management, economic factors and tax considerations.

Operating Activities

Cash provided by operating activities was $4,242, $3,711 and $2,624 in 2024, 2023 and 2022. The increase in 2024 was primarily due to higher cash earnings partially offset by changes in working capital. The increase in 2023 from 2022 was primarily due to higher net earnings and increased collections on accounts receivable.

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Stryker Sustainability Solutions, INC

Physical Address: 1810 West Drake Drive

City: Tempe State: AZ Zip: 85283

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (480) 259-6505 Website: https://sustainability.stryker.com/

Name of Designated Representative (DR): ~~Marissa Richmond~~ Sergio Ochoa

Licensing Company Email: statelicensing1@stryker.com DR Email: ~~marissa.richmond~~@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see Attachment 1

Original Signature (electronic, copies or stamps not accepted)

Date

Date	Entity	Location	State of Discipline	Description of Discipline
2022	Stryker Sustainability Solutions, Inc. ("SSS")	Tempe, AZ	Nevada	SSS received a letter from the Nevada BoP finding that SSS was distributing medical devices in Nevada without a license. The BoP ordered SSS to cease and desist all distribution and ordered the payment of a fine. With guidance from the BoP, SSS paid the fine and initiated license applications in both Nevada and its home state of Arizona. Having not received its Arizona and Nevada applications, SSS received a second letter from the Nevada BoP in early 2023, with further action deferred, by agreement of the BoP and Stryker, pending the issuance of licenses by both Arizona and Nevada.
2023	Stryker Sustainability Solutions, Inc. ("SSS")	Tempe, AZ	Nevada	SSS received a letter from the Nevada BoP finding that SSS was distributing medical devices in Nevada without a license. The BoP ordered SSS to cease and desist all distribution and ordered the payment of a fine. With
2024	Stryker Sustainability Solutions, Inc. ("SSS")	Tempe, AZ	Arizona	As an output of a corporation-wide project to obtain necessary state licenses, Stryker identified its need for licensure and negotiated a civil disciplinary for unpermitted distribution of medical devices. Stryker paid the negotiated penalty and Arizona issued a resident permit.
2024	Stryker Sustainability Solutions, Inc. ("SSS")	Phoenix, AZ	Arizona	As an output of a corporation-wide project to obtain necessary state licenses, Stryker identified its need for licensure and negotiated a civil disciplinary for unpermitted distribution of medical devices. Stryker paid the negotiated penalty and Arizona issued a resident permit.
3/20/2025	Stryker Sustainability Solutions, Inc. ("SSS")	1810 W Drake Dr., Tempe, AZ	Kansas	Stryker Sustainability Solutions, Inc. was fined by the Kansas Board of Pharmacy for distribution of medical devices in the state of Kansas without a license issued by the Kansas BOP.

KRISTIN K. MAYES
Attorney General
Firm State Bar No. 14000

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
Assistant Attorney General
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2005 N. Central Ave., SGD/LES
Phoenix, Arizona 85004-1592
Tel: (602) 542-7983
Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **STRYKER SUSTAINABILITY SOLUTIONS, INC. (Tempe)** **Applicant for Permit (M002150) as a Resident Virtual Manufacturer In the State of Arizona;** **STRYKER SUSTAINABILITY SOLUTIONS, INC. (Phoenix)** **Applicant for Permit (M002160) as a Resident Manufacturer In the State of Arizona;** **HOWMEDICA OSTEONICS, CORP. /STRYKER ORTHOPAEDICS (Tucson)** **Applicant for Permit (W003760) as a Resident Wholesaler In the State of Arizona;** **APPLICANTS**	Case No. 23-0627 **CONSENT AGREEMENT FOR ISSUANCE OF PERMITS AND ORDER FOR CIVIL PENALTY**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.* Stryker Sustainability Solutions ("Stryker Tempe" and "Stryker Phoenix") and Howmedica Osteonics Corp. ("Stryker Orthopaedics") collectively "Applicants", and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Applicant has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Applicant understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Applicant knowingly and voluntarily relinquishes all rights to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Applicant affirmatively agrees that this Consent Agreement shall be irrevocable. Applicant acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

4. Applicant understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Applicant understands this Consent Agreement deals with a Board Complaint involving allegations of unethical conduct against Applicant. The investigation into these allegations against Applicant shall be concluded upon the Board's execution of this Consent Agreement.

6. Applicant acknowledges and agrees that the acceptance of this Consent Agreement is solely to settle this Board matter and the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement and does not preclude the Board from instituting other proceedings as may be appropriate now or in the future.

7. Applicant understands that, except as provided in this Consent Agreement regarding the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement, this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

8. Furthermore, and notwithstanding any language in this Consent Agreement, this Consent Agreement does not preclude in any way any other state agency or officer or political subdivision of this state from instituting proceedings, investigating claims, or taking legal action as may be appropriate now or in the future relating to this matter other matters concerning Applicant, including violations of Arizona's Consumer Fraud Act. Applicant acknowledges that, other than with respect to the Board, this Consent Agreement makes no representations, implied or otherwise, about the views or intended actions of any other state agency or officer or political subdivision of the state relating to this matter or other matters concerning Applicant.

9. This Consent Agreement is effective only when signed by the Executive Director. If this Consent Agreement does not become effective it is withdrawn and shall

be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that if this case proceeds to hearing, Applicant shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. Applicant understands that any violation of this Consent Agreement constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(16) and A.R.S. §32 – 1927.02(A) (1).

13. The parties understand and agree that Portable Document Format and facsimile copies of this Consent Agreement including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

14. Applicant agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY APPLICANT

Dated: 4/12/2024

On Behalf of
Stryker Sustainability Solutions, Inc.
and Howmedica Osteonics Corp.

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Stryker Sustainability Solutions, Inc. operated as a resident virtual manufacturer at two locations in the state of Arizona and Howmedica Osteonics Corp. operated as a wholesaler at one location in the state of Arizona. These three locations are not currently permitted in the state of Arizona.

3. During an inspection of a third Arizona-based Applicant location that held a permit but required a different type of permit, the Board identified potential unpermitted activity involving a different location and opened an investigation.

4. Applicant, through counsel, informed the Board that in fact, it was likely that several additional locations required permits. Applicant was already in the midst of a multi-year enterprise-wide project to rectify this oversight and voluntarily identified to the Board those locations within Arizona that Applicant believed required permitting.

5. In total, Applicant filed 28 permit applications with the Board and met with the Board on multiple occasions to discuss an efficient and orderly process to resolve all unpermitted activity at Applicant's locations that held or sought new permits.

6. Applicant acknowledges that it has manufactured and sold numerous devices from and into Arizona from unpermitted locations.

7. Applicant has 28 pending permit applications with the Board, which include administratively incomplete applications and applications that are substantively complete and ready for issuance. Three of these pending permit applications related to operations located within the State of Arizona.

CONCLUSIONS OF LAW

1. The Board asserts jurisdiction over the subject matter and over Applicant pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may deny a permit to an Applicant who has engaged in unethical conduct. A.R.S. § 32-1927.02(P).

3. The conduct and circumstances described above provide grounds for Board to impose discipline under A.R.S. §32-1927.03 which provides, that a person that resides in any other jurisdiction and that sells a prescription-only drug or device, within or into this state shall hold a valid board-issued permit and which allows the Board to impose a civil penalty for unpermitted activity.

ORDER

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT:

1. Stryker Sustainability Solutions, Inc. and Howmedica Osteonics Corp. shall jointly pay to the Board as a civil penalty the sum of Three Hundred Seventy-Five Thousand Dollars ($375,000/$125,000 per unpermitted location in this state). The civil penalty shall be paid in full to the Board within **Ninety (90) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. **IT IS FURTHER ORDERED, that the Board, through its Executive Director shall immediately grant and issue permits for all substantively complete applications and shall without delay, grant and issue permits for all applications that Applicant shall cause to be substantively completed or resubmitted to the Board in compliance with this Consent Agreement, subject to the following:**

   a. **The Board shall not grant any applications until such time Applicant pays the civil penalty as set forth above and any applicable permit fees.**

b. **The Board shall not grant any application until it has determined through its Executive Director, that the application is substantively complete and that the Applicant has met the minimum requirements for the permit.**

c. **The Board shall not consider any unpermitted activity at any location in deciding whether an application is administratively or substantively complete and shall not deny any application or pursue any other available remedy on the basis of unpermitted activity at any location before the effective date of this Consent Agreement.**

d. For each non-resident location, the Board shall issue a non-disciplinary advisory letter for unpermitted activity.

e. Upon Applicant's execution of and compliance with the terms in this consent agreement, including payment of the amount set forth in paragraph 1 above, all matters arising out of or made in connection with this consent agreement shall be fully resolved.

3. **By entering into the Consent Agreement, Applicant waives its right to appeal. In addition, the Board may seek further remedies as permitted by statute.**

4. With respect to the approximately twenty-five (25) various permit applications pending before the Board filed by or on behalf of Stryker Corporation or its subsidiaries, the parties acknowledge that the applications are in various stages of review by Board staff. Some applications are incomplete awaiting the receipt of additional information. Other applications were administratively closed because requested information was not timely received. Applicant has stated its intention to refile those applications and have all of its facilities come into compliance with Arizona law. **The parties agree that all applications that are otherwise complete and have met the**

requirements for licensure, shall be approved and the permits granted with Advisory Letters issued accordingly with each approved application.

5. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

DATED this 11th day of April, 2024.

ARIZONA STATE BOARD OF PHARMACY

By: Kamlesh Gandhi
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FOREGOING FILED
this 11th day of April, 2024, with:

Arizona State Board of Pharmacy
1110 W. Washington St, Ste 260
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED BY
ELECTRONIC & REGULAR FIRST-CLASS MAIL
this 11th day of April, 2024, to:

Stryker Sustainability Solutions, Inc.
Attn: Marissa Richmond
[redacted]
marissa.richmond@stryker.com

Howmedica Osteonics Corp.
Attn: Cameron Caller
[redacted]
cameron.caller@stryker.com

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Mark Boesen
Michael Raine
Boesen & Snow Law
8501 E. Princess Dr., Ste. 220
Scottsdale, AZ 85255
MBoesen@BSLawUSA.com
MRaine@BSLawUSA.com

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Jeanne Galvin Seth T. Hargraves
Assistant Attorneys General
2005 N, Central Ave, SGD/LES
Phoenix, Arizona 85004-1592
Attorney for the State
LicensingEnforcement@azag.gov

JM Ironell

Doc #11915034

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

March 20, 2025

Shayne Schiedel
Stryker Corporation
1941 Stryker Way, Suite A
Portage, MI, 49002

RE: Case No. 25-038

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $16,390. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

cc:
see next page

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

cc:

Stryker Corporation
3800 E Centre Ave
Portage MI 49002

Stryker Sustainability Solutions, Inc.
1810 W Drake Dr
Tempe AZ 85283

Tornier, Inc.
10801 Nesbitt Ave S
Bloomington IL 55437

TMJ Solutions, LLC
6059 King Dr
Ventura, CA 93003

Physio-Control, Inc.
11811 Willows Rd, NE
Redmond, WA 95052

Physio-Control, Inc.
11811 Willows Dr, NE
Redmond, WA 95052

Howmedica Osteonics Corporation
325 Corporate Dr
Mahwah, NJ 07430

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 25-038
Stryker Corporation (Portage, MI)	)	
Registration # 4-125038	)	
	)	
Stryker Sustainability Solutions, Inc.	)	
(Tempe, AZ)	)	
Registration # 4-125033	)	
	)	
Tornier, Inc. (Bloomington, MN)	)	
Registration # 4-125035	)	
	)	
TMJ Solutions, LLC (Ventura, CA)	)	
Registration # 4-125040	)	
	)	
Physio-Control, Inc. (Redmond, WA)	)	
Registration # 4-125036	)	
Registration # 5-125041	)	
	)	
Howmedica Osteonics Corporation	)	
(Mahwah, NJ)	)	
Registration # 4-125042	)	

SUMMARY ORDER

NOW, on this 20th day of March 2025, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Stryker Corporation ("Applicant"), for application for registration as a manufacturer and a wholesale distributor in the state of Kansas.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On March 10, 2025, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Styker Corporation" located at 3800 E Centre Ave, Portage, Michigan ("Applicant's MI Manufacturer Application").

   a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes," the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas."

   b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 9 unique days from November 4, 2022 to October 10, 2023.

2. On March 10, 2025, the Board received Applicant's application for registration as a non-resident wholesale distributor in the State of Kansas for the manufacturing facility "Styker Sustainability Solutions, Inc." located at 1810 W Drake Dr, Tempe, Arizona ("Applicant's AZ Manufacturer Application").

   a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

   b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on more than 175 unique days from October 3, 2022 to September 29, 2023.

3. On March 10, 2025, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Tornier, Inc." located at 10801 Nesbitt Ave S, Bloomington, Minnesota ("Applicant's MN Manufacturer Application").

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 6 unique days from November 8, 2023 to October 15, 2024.

4. On March 10, 2025, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "TMJ Solutions, Inc." located at 6059 King Dr, Ventura, California ("Applicant's CA Manufacturer Application").

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 27 unique days from July 8, 2022 to October 21, 2024.

5. On March 10, 2025, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas ("Applicant's WA Manufacturer Application") and Applicant's application for registration as a non-resident wholesale distributor ("Applicant's WA Distributor Application") for the facility "Physio-Control, Inc." located at 11811 Willows Rd, NE,

and 11811 Willows Dr, NE, respectively, in Redmond, Washington.

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant report shipping into Kansas on 81 unique days from October 2, 2023 to October 28, 2024.

6. On March 10, 2025, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Howmedica Osteonics Corporation" located at 325 Corporate Dr, Mahwah, New Jersey ("Applicant's NJ Manufacturer Application").

a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping to 71 unique facilities.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against the application of any manufacturer or wholesale distributor upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Pursuant to K.S.A. 65-1643(g), it shall be unlawful for any person to manufacture any drugs or devices without first obtaining a registration from the Board.

5. Applicant's act of shipping into Kansas as a non-resident wholesale distributor prior to being registered as a wholesale distributor is a violation of K.S.A. 65-1643(c) and is a basis to take action against Applicant's WA Distributor Application pursuant to K.S.A. 65-1627(f).

6. Applicant's act of operating as a non-resident manufacturer in Kansas from six unique facilities prior to being registered as a manufacturer is a violation of K.S.A. 65-1643(g) and is a basis to take action against Applicant's MI Manufacturer Application, Applicant's AZ Manufacturer Application, Applicant's MN Manufacturer Application, Applicant's CA Manufacturer Application, Applicant's WA Manufacturer Application, and Applicant's NJ Manufacturer Application pursuant to K.S.A. 65-1627(f)(6).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's MI Manufacturer Application, Applicant's AZ Manufacturer Application, Applicant's MN Manufacturer Application, Applicant's CA Manufacturer Application, Applicant's WA Manufacturer Application, Applicant's WA Distributor Application, and Applicant's NJ Manufacturer Application are hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of $16,390. Applicant has 30 days from the date of this order to pay the fine and the registrations shall be issued upon receipt.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

3/20/2025
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 20th day of March 2025, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Shayne Schiedel
Stryker Corporation
1941 Stryker Way, Suite A
Portage, MI, 49002

Stryker Corporation
3800 E Centre Ave
Portage MI 49002

Stryker Sustainability Solutions, Inc.
1810 W Drake Dr
Tempe AZ 85283

Tornier, Inc.
10801 Nesbitt Ave S
Bloomington IL 55437

TMJ Solutions, LLC
6059 King Dr
Ventura, CA 93003

Physio-Control, Inc.
11811 Willows Rd, NE
Redmond, WA 95052

Physio-Control, Inc.
11811 Willows Dr, NE
Redmond, WA 95052

Howmedica Osteonics Corporation
325 Corporate Dr
Mahwah, NJ 07430

Kansas Board of Pharmacy Staff

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: Tempe State: AZ Zip: 49002

Name: Not Applicable

Address: _____ City: _____ State: _____ Zip: 85283

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Michigan

Parent Company (if any): _____

Corporation Name: Stryker Corporation

Mailing Address: 1941 Stryker Way

City: Portage State: MI Zip: 49002

Telephone: _____ Email: marissa.richmond@stryker.com

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Stryker Corporation

Corporation/Organization Name: Stryker Sustainability Solutions, Inc

Mailing Address: 1810 West Drake Drive

City: Tempe State: AZ Zip: 85283

Telephone: 269-385-2600 Email: austin.ke@stryker.com

Contact Person Name: Austin Ke

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: 269-385-2600 Email: austin.ke@stryker.com

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration Attachment 2 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. N/A - publicly trader parent		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** Attachment 3	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** Applicant is 100% owned by Stryker Corp		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** Attachment 4	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ Not Applicable- Applicant is 100% owned by Stryker Corp		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** Not Applicable	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) Attachment 5	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Attachment 6	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Attachment 7	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Attachment 8	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A - FDA Registered		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A - FDA Registered		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stryker Sustainability Solutions, Inc

Facility Name

MARISSA RICHMOND

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

7.17.24

Date

Board Use Only	Date Received: 7/21/25	Amount: $1000 ec

Attachment 2 – FDA Registration



Attachment 3 – Officers

Stryker Sustainability Solutions, Inc (100% owned by Stryker Corp)

Name	Role
Menon, Viju	Officer
Pierce, J. Andrew	Officer

Stryker Corp (Publicly Traded NYSE: SYK)

Name	Title	Role
Fletcher, Robert S.	Vice President, Chief Legal Officer	Officer
Lobo, Kevin A.	Chair, Chief Executive Officer, and President	Officer
Menon, Viju S.	Group President, Global Quality and Operations	Officer
Pierce, J. Andrew	Group President, MedSurg and Neurotechnology	Officer
Stiles, Spencer S.	Group President, Orthopaedics	Officer

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "STRYKER SUSTAINABILITY SOLUTIONS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF NOVEMBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

2804049 8300

SR# 20254657281

Authentication: 205411169

Date: 11-24-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment 4

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to certify:

Entity Name: STRYKER CORPORATION
Entity ID#: 800151233
Entity Type: Domestic Profit Corporation
Initial Filing Date: 02/20/1946
Delayed Effective Date:
Formation Jurisdiction: Michigan
Act Formed Under: 327-1931 Michigan General Corporation Act

That the above referenced entity was validly incorporated and said corporation is validly in existence under the laws of this state.

This certificate is issued in conformity with the Act it is formed under, to attest to the fact that the company is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS ★ Corporations, Securities & Commercial Licensing Bureau ★ TUEBOR CIRCUMSPICE

In testimony whereof, I have hereunto set my hand, in the City of Lansing, on July 15, 2025.

Linda Clegg

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

Certificate Number: 14318
Verify this certificate at: www.michigan.gov/corpverifycertificate

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **STRYKER SUSTAINABILITY SOLUTIONS, INC.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/29/2011, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 07/15/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202507155900875
You may verify this certificate online at https://www.nvsilverflume.gov/home

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/26/2025
Receipt Number: 2025207319
Receipt Amount $: 1000.00

Manufacturer - Manufacturer

PERMIT NO
M002150

EXPIRES
10/31/2027

Issued to :

Stryker Sustainability Solutions, Inc
Stryker Corporation
1810 W DRAKE DRIVE
TEMPE, AZ 85283

Stryker Sustainability Solutions, Inc
1810 W DRAKE DRIVE
TEMPE, AZ 85283

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Stryker Corporation
LICENSE NUMBER : M002150
EXPIRES : 10/31/2027

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

• Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 10/17/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	PHONE (A/C. No. Ext): (312) 381-1000	FAX (A/C. No.):
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570116277899 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31876425	11/01/2025	11/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$500,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 318760-25	11/01/2025	11/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X PhysDamage Self In							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			MWC31875925	11/01/2025	11/01/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		AOS				
A	(Mandatory in NH)			MWXS31876125	11/01/2025	11/01/2026	E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below			Excess WC-MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc

©1988-2015 ACORD CORPORATION. All rights reserved.

Holder Identifier : EOCGL3MAL1MEL1M

Certificate No : 570116277899

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Stryker Sustainablity Solutions MDEG License # (if applicable) _____

Physical Address 1810 W. Drake Dr

City Tempe State AZ Zip 85283

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Sergio Middle C Last Osuna

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1810 W. Drake Dr

City Tempe State AZ Zip 85283

Telephone [redacted] Email sergio.osuna@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Guadalupe Learning Center		1996	
Address	**City**	**State**	**Zip**
9201 S. Avenida del Yaqui	Guadalupe	AZ	85283
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Tempe High School		1994-1996	
Address	**City**	**State**	**Zip**
1730 S. Mill Ave	Tempe	AZ	85281
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2001-09/2025	[redacted]	[redacted]	AZ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Stryker Sustainablity Solutions		06/2001-09/2025	
Business Address	**City**	**State**	**Zip**
1810 W. Drake Dr.	Tempe	AZ	85283
Phone	**Title**	**Number of Employed Hours**	
888-888-3433	Shipping Lead	49,920	
Description of Duties			
Shipping, International shipping, Inventory, Customer Returns, Training New Hires, Procedural Updates, Maintaining Shipping Records.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Sergio C. Osuna, certify that as the MDEG Administrator for

Stryker Sustainability Solutions,

that I (initial that you have read and meet the following requirements):

1. SCO Have a high school diploma or its equivalent;
2. SCO Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SCO Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SCO Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sergio C. Osuna
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/12/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stryker Sustainability Solutions, Inc.
Pharmacy/Wholesaler License # (if applicable): board pending
Physical Address: 1810 W. Drake Dr.
City: Tempe State: AZ Zip: 85283
Mailing Address (if different from physical address):
City: State: Zip:
Telephone: Website:
Licensing Company Email: statelicensing1@stryker.com

Section 2: Personal Information

First: Sergio Middle: C Last: Osuna
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Address: 1810 W. Drake Dr.
City: Tempe State: AZ Zip: 85283
Telephone: [redacted] Email: sergio.osuna@stryker.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Guadalupe Learning Center		1996	
Address	**City**	**State**	**Zip**
9201 S. Avenida del Yaqui	Guadalupe	AZ	85283
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Tempe High School		1994-1996	
Address	**City**	**State**	**Zip**
1730 S. Mill Ave.	Tempe	AZ	85281
Diploma/Degree obtained, if any			
n/a			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2001-present	[redacted]	[redacted]	AZ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Stryker Sustainability Solutions, Inc.			06/2001-present	
Business Address		**City**	**State**	**Zip**
1810 W. Drake Dr.		Tempe	AZ	85283
Phone	**Title**		**Number of Employed Hours**	
888-888-3433	Shipping Lead		49,920	
Description of Duties				
Shipping, international shipping, inventory, customer returns, training new hires, procedural updates, maintaining shipping records				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

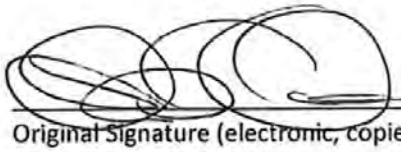
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

11/03/2025

Date

I, Sergio C. Osuna, certify that as the designated representative for

Stryker Sustainability Solutions, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SCO I am at least 21 years of age;
3. SCO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SCO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SCO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SCO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SCO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sergio Osuna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/03/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sergio Osuna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/3/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Sergio OSuna, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/3/2025

Date

Subscribed and Sworn to before me this 3 day of November.

Christopher Wilkinson

Notary Public Signature

CHRISTOPHER WILKINSON
Notary Public - Arizona
Maricopa County
(Seal)
Commission #
My Commission Expires M

Workday ID	First Name	Last Name
2279450	Jorge	Tovar
1461782	Charles	Niemoth
2279479	Mickey	Haynes-Connor
1462683	Natalie	Ward
2279529	Albert	Motley
2279421	Keith	Varty
2279539	Christopher	Beltz
2279553	Meghan	Holter
2279987	Daniel	Fox
2279581	Christy	Rodriguez
2279608	Michael	Scott
2279657	David	Gish
3206627	Jason	Seiger
3220799	Matthew	Sladicka
3232815	Thomas	Kraby
3223024	David	Thompson
3326785	Dawn	Abbott
3314746	Kenneth	Dunham
3884762	Tony	Yu
3943769	Luciano	Alonzo
4125791	Michael	Jakubowski
4652786	Ryan	Yamane
2289369	Paul	Withee
6452794	Cameron	Hansen
6458789	Nathan	Butters
6384787	Ahmad	Massomi
6703829	Andrea	Morgan
6848865	Thomas	Fisher
6720809	Erika	Ajas Suarez
7110194	Ryan	LaFevre
7112562	Alana	Lacy
7121228	Jessica	Gallegos
7204296	Paul	Wallis
7305365	Nicholas	Thomas
7189354	Nicholas	Ferentheil
7190622	ALLEN	JAYARAJ
7191943	Jennifer	Martinez
7192873	Manuel	Hernandez
7101442	Peter	Zibley
7195477	Amy	Wright
7311491	Megan	Wieser
1002657	Lauren	Tanner
1005274	Matthew	Johns
1007875	Araceli	Grossinger
1011100	Victoria	Kim
1013336	Daniel	Foster
1014993	Raymond	Wolniewicz
1016117	Jennifer	Lehrman
1019926	Shelby	Mochal
1021557	Tyler	Hessler
1021908	Michelle	Vycas
1024602	Corey	Miles
1026435	Cameron	Thompson

1026960	Benjamin	Hartman
1027677	Sean	Whitmarsh
1028733	Leda	Belden
1032173	Ana	Hernandez Garcia
1032956	Yan	Chen
1033184	Joshua	Glanzer
1032650	Kristen	Jacokes
1033888	Adam	Hoiness
1034606	Alexandre	Inman
1035547	Adam	Showalter
1034329	Philip	Hsieh
1039789	Morgan	Harder
1040102	Gregory	Baraghimian
1040268	Hannah	Churchill
1010254	Stanley	Halikowski
1042641	Wesley	Sanneman
1045624	Alexia	Stewart
1045746	Michelle	Cox
1036351	Scott	Goodin
4407786	Adrienne	Nielsen
1054000	James	Williams
1055689	Madisyn	Forst
1057054	Natalie	Verdiner
1057626	William	Drubka
1058274	Kambiz	Weaver Salazar
1060856	Shan	Siddiqui
1064077	Andrea	Kretzmann
1064704	Taylor	Aschenbrener
1064797	Stephanie	Galati
1062835	Ajay	Panwar
1008169	Jacob	Schuler
1069608	Matthew	Rivera
1070202	Anum	Puškar
1072476	Ashley	Oscislawski
1072455	Savanna	Taj
1072886	Christian	Winter
1073930	VARIAN	Vital
1075417	Bryce	Vegh
1060932	Abby	Johnson
1073155	Nicholas	Wesley
1074373	Corinne	Stordahl
1078788	Lauren	Postel
1078922	Darian	Thompson
1079342	Theresa	Marks
1079923	Ethan	Langland
2279392	Sergio	Osuna
2279415	Jose	Zepeda
2279473	Luisa	Mejia
3223113	Lisa	Martinez
3226326	Anthony	Lanka
3226592	James	Wilson
3563371	Joel	Villa
3622659	Dorothy	Mashburn
4126786	Trevor	Smithson

3336322	Kirkpatrick	Lindsey
3944795	James	Petrosuis
4937787	Elizabeth	Fisher
6865916	Ana	Flamenco
7109257	Alison Rose	Llave
7173183	Marissa	Richmond
7191205	Leticia	Hernandez
7190130	Korey	Peterson
7151183	Alex	Hernandez
1002142	Stephen	Morris
3357313	Chad	Hollender
1003484	Matthew	Thurman
1002905	Sergio	Osuna
1016115	Alaina	Pamintuan
1022389	Emily	Forbes
1022349	Haley	Brausch
1024069	Daniel	Coburn
1038072	Michael	Ku
1039194	Wesley	Tong
1032174	Angel	Olguin
1041579	Raquel	Quiroz
1042382	Mitchell	Hymas
1045221	Paul	Case
1046871	Sean	Guthrie
1047411	Gabriel	Muniz
1047924	April	Kapp
1048775	Felicia	Florez
3727760	Richard	Sugihara
1024327	David	Marschke
1046046	Mark	Sanchez
1058877	Mercedes	Garcia
1069909	Samuel	Thomasson
1064508	Nurosa	Lan
1075671	Melissa	Tepatlan
1076004	Gary	Sanderer
1063914	Alexander	Wilhelm
1078715	Steven	Boggs
1079143	Casey	Sheldon

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	**38-1239739**
(State of Incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	**49002**
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	**SYK**	**New York Stock Exchange**
2.125% Notes due 2027	**SYK27**	**New York Stock Exchange**
3.375% Notes due 2028	**SYK28**	**New York Stock Exchange**
0.750% Notes due 2029	**SYK29**	**New York Stock Exchange**
2.625% Notes due 2030	**SYK30**	**New York Stock Exchange**
1.000% Notes due 2031	**SYK31**	**New York Stock Exchange**
3.375% Notes due 2032	**SYK32**	**New York Stock Exchange**
3.625% Notes due 2036	**SYK36**	**New York Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $123,147,898,554 at June 30, 2024. There were 381,579,123 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2025 Annual Meeting of Shareholders (the 2025 proxy statement) are incorporated by reference into Part III.

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PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity We do what's right

Accountability We do what we say

People We grow talent

Performance We deliver

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and artificial intelligence-assisted virtual care platform technology; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics and Spine, the Interventional Spine (IVS) portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. In addition, we changed the name of our "Orthopaedics and Spine" operating segment to "Orthopaedics."

Quarterly Net Sales - Enabling Technologies

	2024	2023	2022
Mar 31	$ 30	$ 31	$ 30
Jun 30	$ 31	$ 32	$ 25
Sep 30	$ 59	$ 54	$ 44
Dec 31	$ 32	$ 32	$ 32
Total	**$ 152**	**$ 149**	**$ 131**

Quarterly Net Sales - IVS

	2024	2023	2022
Mar 31	$ 98	$ 77	$ 65
Jun 30	$ 98	$ 83	$ 73
Sep 30	$ 117	$ 84	$ 72
Dec 31	$ 100	$ 83	$ 72
Total	**$ 413**	**$ 327**	**$ 282**

Quarterly Net Sales - Spinal Implants

	2024	2023	2022
Mar 31	$ 171	$ 178	$ 183
Jun 30	$ 178	$ 161	$ 193
Sep 30	$ 186	$ 180	$ 182
Dec 31	$ 172	$ 176	$ 175
Total	**$ 707**	**$ 713**	**$ 733**

Net Sales by Reportable Segment

	2024		2023		2022	
MedSurg and Neurotechnology	$ 13,518	60 %	$ 12,163	59 %	$ 10,893	59 %
Orthopaedics	9,077	40	8,335	41	7,556	41
Total	**$ 22,595**	**100 %**	**$ 20,498**	**100 %**	**$ 18,448**	**100 %**

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and artificial intelligence-assisted virtual care platform technology (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson MedTech (a subsidiary of Johnson & Johnson) and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson Medtech, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2024		2023		2022	
Instruments	$ 2,834	21 %	$ 2,534	21 %	$ 2,245	21 %
Endoscopy	3,389	25	3,068	25	2,759	25
Medical	3,852	28	3,459	28	3,031	28
Neurovascular	1,307	10	1,226	11	1,200	11
Neuro Cranial	2,136	16	1,876	15	1,658	15
Total	$ 13,518	100 %	$ 12,163	100 %	$ 10,893	100 %

In 2024 Instruments launched SurgiCount+ powered by Triton, which combines our existing sponge counting technology with artificial intelligence and quantifying blood loss software. We also launched CoPilot, which combines with our Spine Q guidance system to help surgeons plan and perform certain spinal procedures, including supporting bone resection, pedicle preparation and screw delivery.

In addition we completed the acquisition of Vertos Medical, Inc., a leader in interventional pain management solutions for chronic lower back pain caused by lumbar spinal stenosis. The acquisition of Vertos is complementary to our Interventional Spine business as we continue to focus on advanced pain procedures.

Endoscopy continued to deliver its 4K 1788 Camera platform to the market. Our 1788 Camera platform features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat and can be used to visualize indocyanine green and Cytalux.

Medical launched the LIFEPAK 35 monitor/defibrillator, our next generation platform designed to optimize care with new clinical features such as the new Glasgow 30.4 algorithm, cprINSIGHT, 15-lead monitoring capabilities, and STJ insight and mapping. LIFEPAK 35 combines a modern intuitive touch screen display and increased processing power with Bluetooth and WiFi data connectivity.

Medical also completed the acquisition of care.ai, a virtual care and ambient intelligence solutions platform. care.ai adds complementary technology that is expected to integrate seamlessly with the Vocera platform (Vocera) and Stryker's devices, providing customers with an enterprise-wide ecosystem that is intended to deliver dynamic clinical workflows and further the development of smart care facilities.

Neurovascular initiated a targeted launch of the Surpass Elite Flow Diverting Stent (FDS) in the U.S. and South Korea. Surpass Elite FDS is designed to reduce thrombin generation when compared to unmodified stents. Additionally, Neurovascular launched Surpass Evolve FDS in Japan. The Stryker FDS platform is designed to effectively treat aneurysms by redirecting blood flow away from the aneurysm to promote healing.

Orthopaedics

Orthopaedics products primarily include implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technologies, products and services they need to support each patient's clinical challenge.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, Johnson & Johnson MedTech and Smith & Nephew.

Composition of Orthopaedics Net Sales

	2024		2023		2022	
Knees	$ 2,447	27 %	$ 2,273	27 %	$ 1,997	26 %
Hips	1,704	19	1,544	18	1,413	19
Trauma and Extremities	3,507	39	3,147	38	2,807	37
Spinal Implants	707	8	713	9	733	10
Other	712	8	658	8	606	8
Total	$ 9,077	100 %	$ 8,335	100 %	$ 7,556	100 %

In 2024 we continued the full commercial launch of our Triathlon Hinge revision knee system. Triathlon Hinge received approval in August of 2023 and is now released in the U.S., Canada and New Zealand. We also continued delivering growth in total hip arthroplasty, particularly in the primary segment where Direct Anterior Reconstructive Technology and Mako Total Hip can help to reduce, if not eliminate, a surgeon's use of intraoperative fluoroscopy during direct anterior hip procedures. With the acquisition of SERF SAS, we strengthened distribution in key European markets and continue to scale differentiated solutions such as the Novae monolithic dual mobility cup engineered to deliver greater hip stability and reduce dislocation risk.

We continued to expand our global footprint of Mako SmartRobotics™ in 2024 which is now sold in more than 45 countries. To date more than one million robotic Mako Total Knees and 1.5 million robotic procedures across Total Hips, Total Knees and Partial Knees have been performed globally. Stryker's Joint Replacement division also launched the "Scan. Plan. Mako Can." direct to patient campaign, accelerating awareness of Mako technology in the U.S.

Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

In December 2024 we performed our first Mako Shoulder procedure using robotic-arm assistance to remove bone, prepare the glenoid surface and enable positioning and placement of the Perform Reversed Glenoid implant.

In 2024 Trauma launched Pangea, a comprehensive variable angle plating portfolio designed to optimize plate fit to bone utilizing simple, intuitive instrumentation that enhances ease of use and reproducibility. These combined solutions empower Stryker to deliver a complete portfolio across all trauma segments.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources, however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2024 we owned approximately 5,600 United States patents and approximately 8,600 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the

summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2022, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. Any resulting investigations and prosecutions potentially carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2024 we had approximately 53,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups, which are open to all employees, to focus on creating community and belonging

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer to our executive officers.

Information about our Executive Officers

As of January 31, 2025

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	59	Chair, Chief Executive Officer and President	2011
Yin C. Becker	61	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	59	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	63	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	55	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	54	Vice President, Chief Legal Officer	2019
Viju S. Menon	57	Group President, Global Quality and Operations	2018
J. Andrew Pierce	51	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	48	Group President, Orthopaedics	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2025 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our or Inari Medical, Inc.'s ("Inari") products;
- geopolitical risks, including from international conflicts, which could, among other things, lead to increased market volatility;

- pricing pressures generally, including cost-containment measures that have adversely affected and could in the future adversely affect the price of or demand for our or Inari's products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products, including Inari products, by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in coverage and reimbursement levels from third-party payors;
- changes in the competitive environment;
- breaches, failures or other disruptions of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes, including our acquisition of Inari;
- our ability to realize any anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- uncertainties as to the timing of the tender offer for shares of Inari common stock and the subsequent merger with Inari;
- uncertainties as to how many of Inari's stockholders will tender their shares in the tender offer;
- the failure to satisfy any of the closing conditions to the acquisition of Inari, including the expiration or termination of the Hart-Scott-Rodino Antitrust Improvements Act waiting period (and the risk that such governmental approval may result in the imposition of conditions that could adversely affect the expected benefits of the transaction);
- delays in consummating the acquisition of Inari or the risk that the transaction may not close at all;
- unexpected liabilities, costs, charges or expenses in connection with the acquisition of Inari;
- the effects of the proposed Inari transaction (or the announcement thereof) on the parties' relationships with employees, customers, other business partners or governmental entities; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to the risk of product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to any raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to, among other things, the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, business disruptions, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer, possibly materially. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, in recent years, the market has experienced inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may in the future result in, high interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may in the future experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, high interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors, including changes in reimbursement practices and coverage policies and third-party payor cost containment measures: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in coverage or reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. Coverage policies and reimbursement levels can vary across the payer community globally, regionally, and locally, and may affect which products customers purchase, the market acceptance rate for new technologies and the prices customers are willing to pay for those products in a particular jurisdiction. Furthermore, any changes to the coverage or reimbursement landscape, or adverse decisions relating to our products by administrators of these systems could significantly reduce reimbursement for procedures using our products or result in denial of reimbursement for those products, which could adversely affect customer demand, or the price customers are willing to pay for such products. Public and private payers have challenged, and are expected to continue to challenge, prices charged for medical products and services. Such downward pricing pressures from any or all of these payers may result in an adverse effect on our business, results of operations, financial condition and cash flows. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition and the regulatory burden in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation, new product development and improvement of existing products. New business models, products and surgical procedures, as well as improvements to existing products, are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, including by our existing competitors and new market entrants, which could adversely impact demand for certain of our existing products. The success of our products and services depends on, among other things, our ability to properly identify customer needs and predict future needs; innovate and develop new technologies, services and applications at an accelerated pace; and appropriately allocate our research and development spending to products and services with higher growth. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We work with healthcare professionals in a transparent and responsible manner and seek to maintain these relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in coverage or reimbursement levels from third-party payors in the United States and other countries; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with

the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability and uncertainty; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which has increased the risks we are subject to.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Furthermore, numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Emerging technologies such as generative artificial intelligence (AI) may be used by malicious actors to create more targeted phishing narratives, spread disinformation about us or our products or otherwise strengthen social engineering capabilities. Some of our products, services, and information technology systems contain or use open-source software which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, unauthorized access to, and disruptions of, products or systems. While such breaches, unauthorized access and disruptions have not had a material effect on us to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity or other technology related incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment and customer requirements related to information security, data collection and use, and privacy become increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability.

Hardware and software failures or delays in our key information technology systems, networks, processes or sites could disrupt our operations, cause the loss of confidential information or otherwise adversely impact our business. Our systems, networks, processes and sites may be vulnerable to damage, disruptions and shutdown from a variety of sources, including malfunctions in maintenance updates or security patches, design defects, the age of the technology, network failures, modernization or other initiatives, human acts and natural disasters. For example, some of our information technology systems contain legacy third-party software components for which we depend on a layered security

approach to protect against exploitation, which may not be effective. Any such damage or disruptions could also compromise the security of our information systems and networks. These issues can also arise as a result of failures by, or in the software or hardware of, third parties, including networks or service providers, with whom we do business and over whom we have limited or no control. Any disruption or failure of our systems, networks, processes or sites could have a material impact on our business and operations.

If our IT systems, networks or processes are damaged or cease to function properly for any reason, the networks, service providers, hardware or software we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive workforce in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by

governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. It is not possible to predict whether elective medical procedures will be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and may continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm, among other things.

Our use of AI and other emerging technologies could adversely impact our business and financial results: We have begun to deploy AI and other emerging technologies in various facets of our operations and we continue to explore further use cases. The rapid advancement of these technologies presents opportunities for us in research, manufacturing, commercialization, and other business endeavors, but also entails risks, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. In addition, any disruption or failure in the AI functionality we incorporate into our business activities, products or services could adversely impact our business or result in delays or errors in our product offerings. The legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity and privacy and data protection. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant costs on us and limit our ability to effectively develop, deploy or use AI technologies. Furthermore, if we are unable to effectively manage the use of AI technologies by our employees and service providers, our confidential information, intellectual property and reputation could be put at risk. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with prior pandemics, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks that revise the existing profit allocation and nexus rules (Pillar 1) and ensure a minimal level of taxation (Pillar 2), respectively. In 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws are effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes, could increase tax expense in future periods.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to healthcare or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. Both in the U.S. and internationally, governmental authorities may make legislative or administrative reforms to existing reimbursement programs, make adverse decisions relating to our

products' coverage or reimbursement, or make changes to patient access to healthcare, all of which could adversely impact the demand for and usage of our products or the prices that our customers are willing to pay for them. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. For example, governmental authorities in the United States and internationally have or are considering adopting regulations on the use of per- and polyfluoroalkyl substances. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We may also be subject to legal obligations in some countries that require disclosure or sharing of proprietary information. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws have in the past resulted and could in the future result in investigations, litigation or government proceedings, and we have been and may in the future be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. For example, in 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and enforcement and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial

Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive) mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The European Product Liability Directive was revised in 2024 and will become fully adopted into each member state's national laws by 2026. The revised Product Liability Directive and Collective Redress Directive exposes us to additional litigation risks and could result in significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on intellectual proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents and the expiration of patents may lead to a loss of exclusive rights and/or increased competition.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties, financing transactions in currencies other than the United States Dollar and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars. In recent years, currency exchange rates have been especially volatile, and these currency fluctuations have affected, and may continue to affect, our results of operations.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve, including in diverging directions. On occasion, we announce new initiatives and make disclosures, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest and applicable regulatory requirements, which include environment and sustainability, workforce-related issues, diversity, equity and inclusion and supply chain management, among others. Implementation of these initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in, among other things, reduced demand for our products, reduced profits, increased investigations and litigation and an increased risk of reputational damage. If we are unable to satisfy evolving criteria, certain investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate or undesirable. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change have increased and are expected to further increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures and flooding, which could cause more significant business and supply chain

interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors periodically. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 27 company-owned and 297 leased locations worldwide including 45 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products.

We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various ongoing proceedings, legal actions and claims arising in the normal course of our business, including proceedings related to product, labor, intellectual property and other matters. Refer to Note 7 to our Consolidated Financial Statements for further information.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2025 there were 2,510 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2024 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2024 was $1,033.

In the fourth quarter 2024 we did not issue shares of our common stock as performance incentive awards to employees. When issued, these shares are not registered under the Securities Act of 1933 based on the conclusion that the awards are not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2019 in our common stock and each of the indices.



Company / Index	2019	2020	2021	2022	2023	2024
Stryker Corporation	$ 100.00	$ 118.17	$ 130.25	$ 120.59	$ 149.29	$ 181.15
S&P 500 Index	$ 100.00	$ 118.40	$ 152.39	$ 124.79	$ 157.59	$ 197.02
S&P 500 Health Care Index	$ 100.00	$ 113.45	$ 143.09	$ 140.29	$ 143.18	$ 146.87

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2024	2023	2022	2021	2020
Net sales	$ 22,595	$ 20,498	$ 18,449	$ 17,108	$ 14,351
Cost of sales	8,155	7,440	6,871	6,140	5,294
Gross profit	$ 14,440	$ 13,058	$ 11,578	$ 10,968	$ 9,057
Research, development and engineering expenses	1,466	1,388	1,454	1,235	984
Selling, general and administrative expenses	7,685	7,111	6,386	6,266	5,163
Amortization of intangible assets	623	635	627	619	472
Goodwill and other impairments	977	36	270	264	215
Total operating expenses	$ 10,751	$ 9,170	$ 8,737	$ 8,384	$ 6,834
Operating income	$ 3,689	$ 3,888	$ 2,841	$ 2,584	$ 2,223
Other income (expense), net	(197)	(215)	(158)	(303)	(269)
Earnings before income taxes	$ 3,492	$ 3,673	$ 2,683	$ 2,281	$ 1,954
Income taxes	499	508	325	287	355
Net earnings	$ 2,993	$ 3,165	$ 2,358	$ 1,994	$ 1,599
Net earnings per share of common stock:					
Basic	$ 7.86	$ 8.34	$ 6.23	$ 5.29	$ 4.26
Diluted	$ 7.76	$ 8.25	$ 6.17	$ 5.21	$ 4.20
Dividends declared per share of common stock	$ 3.240	$ 3.050	$ 2.835	$ 2.585	$ 2.355
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,743	$ 3,053	$ 1,928	$ 3,019	$ 3,024
Accounts receivable, net	3,987	3,765	3,565	3,022	2,701
Inventories	4,774	4,843	3,995	3,314	3,494
Property, plant and equipment, net	3,448	3,215	2,970	2,833	2,752
Total assets	$ 42,971	$ 39,912	$ 36,884	$ 34,631	$ 34,330
Accounts payable	1,679	1,517	1,413	1,129	810
Total debt	13,597	12,995	13,048	12,479	13,991
Shareholders' equity	$ 20,634	$ 18,593	$ 16,616	$ 14,877	$ 13,084
Cash Flow Data					
Net cash provided by operating activities	$ 4,242	$ 3,711	$ 2,624	$ 3,263	$ 3,277
Purchases of property, plant and equipment	755	575	588	525	487
Depreciation	427	393	371	371	340
Acquisitions, net of cash acquired	1,628	390	2,563	339	4,222
Amortization of intangible assets	623	635	627	619	472
Payments of dividends	1,219	1,139	1,051	950	863
Repurchase of common stock	—	—	—	—	—
Other Data					
Number of shareholders of record	2,520	2,518	2,533	2,551	2,597
Approximate number of employees	53,000	52,000	51,000	46,000	43,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Overview of 2024

In 2024 we achieved reported net sales growth of 10.2%. Excluding the impact of acquisitions and divestitures, sales grew 10.2% in constant currency. We reported net earnings of $2,993 and net earnings per diluted share of $7.76. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,700 and adjusted net earnings per diluted share[1] of $12.19 representing growth of 15.0%.

We continued our capital allocation strategy by investing $1,628 in acquisitions and paying $1,219 in dividends to our shareholders.

In 2024 we completed various acquisitions for total consideration of $1,628 in upfront payments, net of cash acquired, as well as $400 of contingent consideration if certain commercial or clinical milestones are achieved. Refer to Note 6 to our Consolidated Financial Statements for further information.

In May 2024 we repaid the outstanding $600 principal amount of the 3.375% senior unsecured notes due May 15, 2024. In September 2024 we issued $750 of 4.250% senior unsecured notes due September 11, 2029, €800 of 3.375% senior unsecured notes due September 11, 2032, $750 of 4.625% senior unsecured notes due September 11, 2034 and €600 of 3.625% senior unsecured notes due September 11, 2036. In November 2024 we repaid the outstanding €500 of floating rate senior notes and in December 2024 we repaid €850 of 0.250% senior unsecured notes.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2024	2023	2022	2024	2023	2022	2024 vs. 2023	2023 vs. 2022
Net sales	$ 22,595	$ 20,498	$ 18,449	100.0 %	100.0 %	100.0 %	10.2 %	11.1 %
Gross profit	14,440	13,058	11,578	63.9	63.7	62.8	10.6	12.8
Research, development and engineering expenses	1,466	1,388	1,454	6.5	6.8	7.9	5.6	(4.5)
Selling, general and administrative expenses	7,685	7,111	6,386	34.0	34.7	34.6	8.1	11.4
Amortization of intangible assets	623	635	627	2.8	3.1	3.4	(1.9)	1.3
Goodwill and other impairments	977	36	270	4.3	0.2	1.5	nm	nm
Other income (expense), net	(197)	(215)	(158)	(0.9)	(1.0)	(0.9)	(8.4)	36.1
Income taxes	499	508	325	nm	nm	nm	(1.8)	56.3
Net earnings	$ 2,993	$ 3,165	$ 2,358	13.2 %	15.4 %	12.8 %	(5.4)%	34.2 %
Net earnings per diluted share	$ 7.76	$ 8.25	$ 6.17				(5.9)%	33.7 %
Adjusted net earnings per diluted share[1]	$ 12.19	$ 10.60	$ 9.34				15.0 %	13.5 %

nm - not meaningful

Geographic and Segment Net Sales

				Percentage Change			
				2024 vs. 2023		2023 vs. 2022	
	2024	2023	2022	As Reported	Constant Currency	As Reported	Constant Currency
Geographic:							
United States	$ 16,943	$ 15,257	$ 13,638	11.0 %	11.0 %	11.9 %	11.9 %
International	5,652	5,241	4,811	7.9	9.8	8.9	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %
Segment:							
MedSurg and Neurotechnology	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	11.7 %	12.2 %
Orthopaedics	9,077	8,335	7,556	8.9	9.4	10.3	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %

Supplemental Net Sales Growth Information

				Percentage Change									
				2024 vs. 2023					2023 vs. 2022				
						United States	International				United States	International	
MedSurg and Neurotechnology:	2024	2023	2022	As Reported	Constant Currency	As Reported	As Reported	Constant Currency	As Reported	Constant Currency	As Reported	As Reported	Constant Currency
Instruments	$ 2,834	$ 2,534	$ 2,245	11.9 %	12.1 %	12.5 %	9.5 %	10.6 %	12.9 %	13.0 %	13.5 %	10.4 %	11.8 %
Endoscopy	3,389	3,068	2,759	10.5	11.0	11.1	7.7	10.7	11.2	11.7	11.9	8.0	9.9
Medical	3,852	3,458	3,031	11.4	11.7	14.6	(2.0)	(0.3)	14.1	14.4	15.0	10.7	12.3
Neurovascular	1,307	1,226	1,200	6.6	8.2	4.7	7.9	10.5	2.2	4.0	8.3	(1.5)	1.5
Neuro Cranial	2,136	1,876	1,658	13.9	14.1	15.0	8.7	10.2	13.1	13.4	12.7	15.4	16.8
	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	12.7 %	5.9 %	7.9 %	11.7 %	12.2 %	13.1 %	7.2 %	9.2 %
Orthopaedics:													
Knees	$ 2,447	$ 2,273	$ 1,997	7.6 %	8.2 %	6.7 %	10.4 %	12.2 %	13.8 %	14.4 %	12.3 %	18.5 %	20.9 %
Hips	1,704	1,544	1,413	10.3	11.3	7.2	15.9	18.4	9.3	10.4	10.3	7.5	10.7
Trauma and Extremities	3,507	3,147	2,807	11.4	11.6	12.6	8.3	9.1	12.1	12.2	12.9	10.1	10.5
Spinal Implants	707	713	733	(0.7)	(0.3)	(2.1)	2.5	3.8	(2.7)	(2.0)	(2.2)	(4.1)	(3.4)
Other	712	658	606	8.1	9.6	7.3	10.1	15.4	8.6	9.5	2.9	25.8	32.3
	$ 9,077	$ 8,335	$ 7,556	8.9 %	9.4 %	8.4 %	10.2 %	12.0 %	10.3 %	10.9 %	10.0 %	11.1 %	13.1 %
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.0 %	7.9 %	9.8 %	11.1 %	11.8 %	11.9 %	8.9 %	10.9 %

Note: In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics, the interventional spine portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. Neuro Cranial includes sales related to interventional spine of $413, $327 and $282 for 2024, 2023 and 2022. Other Orthopaedics includes sales related to Enabling Technologies of $152, $149 and $131 for 2024, 2023 and 2022. In the first quarter 2024 a product line previously included in Instruments has been reclassified to Endoscopy to align with a change in our internal reporting structure. We have reflected these changes in all historical periods presented.

Consolidated Net Sales

Consolidated net sales in 2024 increased 10.2% as reported and 10.7% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.5% impact of acquisitions and divestitures, net sales in constant currency increased by 9.1% from increased unit volume and 1.1% due to higher prices. The unit volume increase was primarily due to higher shipments across all businesses.

Consolidated net sales in 2023 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 10.9% from increased unit volume and 0.6% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses and most Orthopaedics businesses.

MedSurg and Neurotechnology Net Sales

MedSurg and Neurotechnology net sales in 2024 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.4% impact of acquisitions and divestitures, net sales in constant currency increased by 9.5% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

MedSurg and Neurotechnology net sales in 2023 increased 11.7% as reported and 12.2% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.3% impact of acquisitions and divestitures, net sales in constant currency increased by 10.2% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

Orthopaedics Net Sales

Orthopaedics net sales in 2024 increased 8.9% as reported and 9.4% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.7% impact of acquisitions and divestitures, net sales in constant currency increased by 8.7% from increased unit volume. The unit volume increase was due to higher shipments across all Orthopaedics businesses.

Orthopaedics net sales in 2023 increased 10.3% as reported and 10.9% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.6%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 11.9% from increased unit volume partially offset by 1.1% due to lower prices. The unit volume increase was due to higher shipments across most Orthopaedics businesses.

Gross Profit

Gross profit was $14,440, $13,058 and $11,578 in 2024, 2023, and 2022. The key components of the change were:

	Gross Profit Percent Net Sales
2022	**62.8 %**
Sales pricing	20 bps
Volume and mix	100 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	10 bps
2023	**63.7 %**
Sales pricing	40 bps
Volume and mix	60 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	(20) bps
Structural optimization and other special charges	(20) bps
2024	**63.9 %**

Gross profit as a percentage of net sales increased to 63.9% in 2024 from 63.7% in 2023 due to higher sales pricing and favorable volume partially offset by higher manufacturing and supply chain costs primarily due to inflationary pressures impacting fixed and variable manufacturing costs as well as higher amortization of inventory stepped up to fair value.

Gross profit as a percentage of net sales increased to 63.7% in 2023 from 62.8% in 2022 due to higher sales pricing and favorable volume offset by higher manufacturing and supply chain costs primarily due to higher raw material costs in the first six months of 2023 and supply chain inefficiencies.

While segment mix was not a significant driver of the change in gross profit as a percent of net sales between 2024, 2023 and 2022, we generally expect segment mix to have an unfavorable impact for the foreseeable future as we anticipate more rapid sales growth in our lower gross margin MedSurg and Neurotechnology segment than our Orthopaedics segment.

Research, Development and Engineering Expenses

Research, development and engineering expenses as a percentage of net sales in 2024 decreased to 6.5% from 6.8% in 2023 primarily due to lower spend on medical device regulations in the European Union.

Research, development and engineering expenses as a percentage of net sales in 2023 decreased to 6.8% from 7.9% in 2022 primarily due to increased spending for product launches, the write-off of certain intangible assets and higher spend related to the new medical device regulations in the European Union in 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses as a percentage of net sales in 2024 decreased to 34.0% from 34.7% in 2023 primarily due to continued spend discipline and lower charges for structural optimization and certain legal matters partially offset by higher acquisition-related costs.

Selling, general and administrative expenses as a percentage of net sales in 2023 of 34.7% remained relatively flat with 34.6% in 2022 as charges of $132 related to share-based awards for Vocera employees that vested upon our acquisition in 2022 were partially offset by disciplined increases in spend and investments in 2023 to support our growth, including sales growth incentives and increased spend on travel and meetings. In addition, in 2022 we determined that certain commercial and regulatory milestones related to technology acquired in the purchase of Mobius Imaging and Cardan Robotics were no longer probable of being achieved and recorded $110 to reduce the fair value of contingent consideration.

Amortization of Intangible Assets

Amortization of intangible assets was $623, $635 and $627 in 2024, 2023 and 2022. These amounts include amortization related to intangible assets acquired in 2024 from various acquisitions, 2023 from Cerus Endovascular Limited (Cerus) and 2022 from Vocera. Refer to Notes 6 and 8 to our Consolidated Financial Statements for further information.

Goodwill and Other Impairments

In 2024 and 2022 we recorded goodwill impairment charges of $456 and $216 related to our Spine business.

In 2024 we recognized an estimated loss of $362 as a result of classifying certain assets in our Spinal Implants business as held for sale. Refer to Notes 8, 16 and 17 to our Consolidated Financial Statements for further information.

In 2024, 2023 and 2022 we recorded other impairments of $159, $36 and $54. Refer to Notes 15 and 16 to our Consolidated Financial Statements for further information.

Operating Income

Operating income was $3,689, $3,888 and $2,841 in 2024, 2023 and 2022. Operating income decreased as a percentage of sales to 16.3% in 2024 from 19.0% in 2023 and increased from 15.4% in 2022. Refer to the comments above for discussion of the primary drivers of the change.

MedSurg and Neurotechnology operating income as a percentage of net sales increased to 29.6% in 2024 from 28.5% in 2023. MedSurg and Neurotechnology operating income as a percentage of net sales increased to 28.5% in 2023 from 26.0% in 2022. Orthopaedics operating income as a percentage of net sales increased to 28.5% in 2024 from 27.2% in 2023. Orthopaedics operating income as a percentage of net sales increased to 27.2% in 2023 from 29.1% in 2022. The key components of the change were:

	Operating Income Percent Net Sales	
	MedSurg and Neurotechnology	Orthopaedics
2022	**26.0 %**	**29.1 %**
Sales pricing	70 bps	(30) bps
Volume	100 bps	80 bps
Manufacturing and supply chain costs	90 bps	(220) bps
Research, development and engineering expenses	50 bps	20 bps
Selling, general and administrative expenses	(60) bps	(40) bps
2023	**28.5 %**	**27.2 %**
Sales pricing	70 bps	0 bps
Volume	40 bps	70 bps
Manufacturing and supply chain costs	(40) bps	(20) bps
Research, development and engineering expenses	0 bps	10 bps
Selling, general and administrative expenses	40 bps	70 bps
2024	**29.6 %**	**28.5 %**

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2024 from 2023 was primarily driven by higher unit volumes, higher prices and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2023 from 2022 was primarily driven by higher unit volumes, higher prices and lower manufacturing and supply chain costs due to supply chain challenges impacting capital products in our MedSurg businesses in 2022 which improved in 2023 partially offset by higher selling, general and administrative expenses as a percentage of sales due to continued investments including sales growth incentives and a more normalized cadence of travel and meetings.

The increase in Orthopaedics operating income as a percentage of net sales for 2024 from 2023 was primarily driven by higher sales volumes and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The decrease in Orthopaedics operating income as a percentage of net sales for 2023 from 2022 was primarily driven by higher higher manufacturing and supply chain costs primarily due to increased inventory reserves partially offset by higher unit volumes.

Other Income (Expense), Net

Other income (expense), net was ($197), ($215) and ($158) in 2024, 2023 and 2022. The decrease in net expense in 2024 from 2023 was primarily due to higher interest income partially offset by lower interest expense in 2024. The increase in net expense in 2023 from 2022 was primarily due to the release of accrued interest of $50 in 2022 related to the effective settlement of the United States federal income tax audit for years 2014 through 2018. Refer to Note 11 to our Consolidated Financial Statements for further information and higher interest income in 2023.

Income Taxes

Our effective tax rate was 14.3%, 13.8% and 12.1% for 2024, 2023 and 2022. The effective income tax rate for 2024 decreased from 2023 due to the 2024 deferred tax benefit on the outside basis difference related to the anticipated sale of the Spinal Implants business partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. The effective income tax rate for 2023 increased from 2022 due to the 2022 effective settlement of the United States federal income tax audit for years 2014 through 2018 and the 2022 reversal of deferred income tax on undistributed earnings of foreign subsidiaries partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. Additionally, the effective income tax rates for 2024, 2023 and 2022 reflect the continued lower effective income tax rates as a result of our European operations and certain discrete tax items.

The Organisation for Economic Cooperation and Development (OECD), which represents a coalition of member countries, has put forth two proposed base erosion and profit shifting frameworks that revise the existing profit allocation and nexus rules (Pillar One) and ensure a minimal level of taxation (Pillar Two). On December 12, 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws became effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes could increase tax expense in future periods.

Net Earnings

Net earnings for 2024 increased to $2,993 or $7.76 per diluted share from $3,165 or $8.25 per diluted share in 2023 and $2,358 or $6.17 per diluted share in 2022. Refer to the comments above for discussion of the primary drivers of the change.

Non-GAAP Financial Measures

We supplement the reporting of our financial information determined under accounting principles generally accepted in the United States (GAAP) with certain non-GAAP financial measures, including percentage sales growth in constant currency; percentage organic sales growth; adjusted gross profit; adjusted selling, general and administrative expenses; adjusted research, development and engineering expenses; adjusted operating income; adjusted other income (expense), net; adjusted income taxes; adjusted effective income tax rate; adjusted net earnings; and adjusted net earnings per diluted share (Diluted EPS). We believe these non-GAAP financial measures provide meaningful information to assist investors and shareholders in understanding our financial results and assessing our prospects for future performance. Management believes percentage sales growth in constant currency and the other adjusted measures described above are important indicators of our operations because they exclude items that may not be indicative of or are unrelated to our core operating results and provide a baseline for analyzing trends in our underlying businesses. Management uses these non-GAAP financial measures for reviewing the operating results of reportable business segments and analyzing potential future business trends in connection with our budget process and bases certain management incentive compensation on these non-GAAP financial measures. To measure percentage sales growth in constant currency, we remove the impact of changes in foreign currency exchange rates that affect the comparability and trend of sales. Percentage sales growth in constant currency is calculated by translating current and prior year results at the same foreign currency exchange rate. To measure percentage organic sales growth, we remove the impact of changes in foreign currency exchange rates, acquisitions and divestitures, which affect the comparability and trend of sales. Percentage organic sales growth is calculated by translating current year and prior year results at the same foreign currency exchange rates excluding the impact of acquisitions and divestitures. To measure earnings performance on a consistent and comparable basis, we exclude certain items that affect the comparability of operating results and the trend of earnings. The income tax effect of each adjustment was determined based on the tax effect of the jurisdiction in which the related pre-tax adjustment was recorded. These adjustments are irregular in timing and may not be indicative of our past and future performance. The following are examples of the types of adjustments that may be included in a period:

1. *Acquisition and integration-related costs*. Costs related to integrating recently acquired businesses (e.g., costs associated with the termination of sales relationships, employee retention and workforce reductions, manufacturing integration costs and other integration-related activities), changes in the fair value of contingent consideration, amortization of inventory stepped-up to fair value, specific costs (e.g., deal costs and costs associated with legal entity rationalization) related to the consummation of the acquisition process and legal entity rationalization and acquisition-related tax items.
2. *Amortization of purchased intangible assets*. Periodic amortization expense related to purchased intangible assets.
3. *Structural optimization and other special charges*. Costs associated with employee retention and workforce reductions, the closure or transfer of manufacturing and other facilities (e.g., site closure costs, contract termination costs and redundant employee costs during the work transfers), product line exits (primarily inventory, long-lived asset and specifically-identified intangible asset write-offs), certain long-lived and intangible asset write-offs and impairments and other charges.
4. *Medical device regulations*. Costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the new medical device reporting regulations and other requirements of the European Union.
5. *Recall-related matters*. Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve the Rejuvenate, LFIT V40, Wright legacy hip products and other product recalls.
6. *Regulatory and legal matters*. Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters.

and the amount of favorable awards from settlements.

7. *Tax matters*. Impact of accounting for certain significant and discrete tax items.

Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names. These adjusted financial measures should not be considered in isolation or as a substitute for reported sales growth, gross profit, selling, general and administrative expenses, research, development and engineering expenses, operating income, other income (expense), net, income taxes, effective income tax rate, net earnings and net earnings per diluted share, the most directly comparable GAAP financial measures. These non-GAAP financial measures are an additional way of viewing aspects of our operations when viewed with our GAAP results and the reconciliations to corresponding GAAP financial measures at the end of the discussion of Consolidated Results of Operations below. We strongly encourage investors and shareholders to review our financial statements and publicly-filed reports in their entirety and not to rely on any single financial measure.

The weighted-average diluted shares outstanding used in the calculation of adjusted net earnings per diluted share are the same as those used in the calculation of reported net earnings per diluted share for the respective period.

Reconciliation of the Most Directly Comparable GAAP Financial Measure to Non-GAAP Financial Measure

2024	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 14,440	$ 7,685	$ 1,466	$ 3,689	$ (197)	$ 499	$ 2,993	14.3 %	$ 7.76
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	46	—	—	46	—	12	34	0.2	0.09
Other acquisition and integration-related (a)	—	(107)	(1)	108	—	23	85	0.2	0.22
Amortization of purchased intangible assets	—	—	—	623	—	128	495	1.0	1.28
Structural optimization and other special charges (b)	59	(77)	(2)	138	1	29	110	0.3	0.29
Goodwill and other impairments (c)	—	—	—	877	—	125	852	(0.6)	2.21
Medical device regulations (d)	9	—	(49)	58	—	14	44	0.1	0.11
Recall-related matters (e)	11	(29)	—	40	—	10	30	0.1	0.08
Regulatory and legal matters (f)	—	(36)	—	36	—	7	29	0.1	0.08
Tax matters (g)	—	—	—	—	—	(28)	28	(0.9)	0.07
Adjusted	$ 14,565	$ 7,436	$ 1,414	$ 5,715	$ (196)	$ 819	$ 4,700	14.8 %	$ 12.19

2023	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 13,058	$ 7,111	$ 1,388	$ 3,888	$ (215)	$ 508	$ 3,165	13.8 %	$ 8.25
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	—	—	—	—	—	—	—	—	—
Other acquisition and integration-related (a)	—	(20)	—	20	—	(25)	45	(0.8)	0.12
Amortization of purchased intangible assets	—	—	—	635	—	132	503	1.2	1.31
Structural optimization and other special charges (b)	39	(130)	(1)	170	—	38	132	0.4	0.34
Goodwill and other impairments (c)	—	—	—	36	—	9	27	0.1	0.08
Medical device regulations (d)	2	—	(94)	96	—	22	74	0.2	0.19
Recall-related matters (e)	—	(18)	—	18	—	4	14	—	0.04
Regulatory and legal matters (f)	—	(92)	—	92	—	29	63	0.4	0.16
Tax matters (g)	—	—	—	—	(8)	(51)	43	(1.2)	0.11
Adjusted	$ 13,099	$ 6,851	$ 1,293	$ 4,955	$ (223)	$ 666	$ 4,066	14.1 %	$ 10.60

2022	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 11,578	$ 6,386	$ 1,454	$ 2,841	$ (158)	$ 325	$ 2,358	12.1 %	$ 6.17
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	12	—	—	12	—	3	9	—	0.02
Other acquisition and integration-related (a)	—	(138)	—	138	—	34	104	0.6	0.27
Amortization of purchased intangible assets	—	—	—	627	—	132	495	1.7	1.30
Structural optimization and other special charges (b)	56	(152)	(87)	295	—	61	234	0.8	0.61
Goodwill and other impairments (c)	—	—	—	270	—	5	265	(1.2)	0.70
Medical device regulations (d)	3	—	(137)	140	—	25	115	0.2	0.30
Recall-related matters (e)	—	15	—	(15)	—	(3)	(12)	—	(0.03)
Regulatory and legal matters (f)	—	(76)	—	76	—	7	69	(0.2)	0.18
Tax matters (g)	—	—	—	—	(75)	(9)	(66)	0.1	(0.18)
Adjusted	$ 11,649	$ 6,035	$ 1,230	$ 4,384	$ (233)	$ 580	$ 3,571	14.1 %	$ 9.34

(a) Charges represent certain acquisition and integration-related costs associated with acquisitions, including:

	2024	2023	2022
Termination of sales relationships	$ 4	$ 5	$ 21
Employee retention and workforce reductions	22	6	33
Changes in the fair value of contingent consideration	8	(1)	(135)
Manufacturing integration costs	3	2	32
Stock compensation payments upon a change in control	22	—	132
Other integration-related activities	49	8	55
Adjustments to Operating Income	**$ 108**	**$ 20**	**$ 138**
Charges for acquisition-related tax provisions	—	—	—
Other income taxes related to acquisition and integration-related costs	23	(25)	34
Adjustments to Income Taxes	**$ 23**	**$ (25)**	**$ 34**
Adjustments to Net Earnings	**$ 85**	**$ 45**	**$ 104**

(b) Structural optimization and other special charges represent the costs associated with:

	2024	2023	2022
Employee retention and workforce reductions	$ 23	$ 69	$ 74
Closure/transfer of manufacturing and other facilities	31	50	83
Product line exits	37	22	34
Termination of sales relationships	8	—	—
Other charges	39	29	104
Adjustments to Operating Income	**$ 138**	**$ 170**	**$ 295**
Adjustments to Other Income (Expense), Net	**$ 1**	**$ —**	**$ —**
Adjustments to Income Taxes	**$ 29**	**$ 38**	**$ 61**
Adjustments to Net Earnings	**$ 110**	**$ 132**	**$ 234**

(c) Goodwill and other impairments represent the costs associated with:

	2024	2023	2022
Goodwill impairments	$ 456	$ —	$ 216
Certain long-lived and intangible asset write-offs and impairments	466	26	8
Product line exits (e.g., long-lived asset and specifically-identified intangible asset write-offs)	55	10	46
Adjustments to Operating Income	**$ 977**	**$ 36**	**$ 270**
Adjustments to Income Taxes	**$ 125**	**$ 9**	**$ 5**
Adjustments to Net Earnings	**$ 852**	**$ 27**	**$ 265**

(d) Charges represent the costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the medical device reporting regulations and other requirements of the new medical device regulations in the European Union.

(e) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain recall-related matters.

(f) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters and the amount of favorable awards from settlements.

(g) Benefits / (charges) represent the accounting impact of certain significant and discrete tax items, including:

	2024	2023	2022
Adjustments related to the transfer of certain intellectual properties between tax jurisdictions	$ (185)	$ (89)	$ (182)
Certain tax audit settlements	(1)	24	162
Reversal of deferred income tax on undistributed earnings of foreign subsidiaries	—	—	71
Deferred tax benefit on outside basis related to the anticipated sale of the Spinal Implants business	170	—	—
Other significant and discrete tax items	(12)	14	(60)
Adjustments to Income Taxes	**$ (28)**	**$ (51)**	**$ (9)**
Benefits for certain tax audit settlements	—	(9)	(45)
Other tax related adjustments	—	1	(30)
Adjustments to Other Income (Expense), Net	**$ —**	**$ (8)**	**$ (75)**
Adjustments to Net Earnings	**$ 28**	**$ 43**	**$ (66)**

FINANCIAL CONDITION AND LIQUIDITY

Net cash provided by (used in):	2024	2023	2022
Operating activities	$ 4,242	$ 3,711	$ 2,624
Investing activities	(3,000)	(962)	(2,924)
Financing activities	(525)	(1,594)	(749)
Effect of exchange rate changes	(36)	(28)	(51)
Change in cash and cash equivalents	**$ 681**	**$ 1,127**	**$ (1,100)**

We believe our financial condition continues to be of high quality, as evidenced by our ability to generate substantial cash from operations and to readily access capital markets at competitive rates despite the current macroeconomic environment. Operating cash flow provides the primary source of cash to fund operating needs and capital expenditures. Excess operating cash is used first to fund acquisitions to complement our portfolio of businesses. Other discretionary uses include dividends and share repurchases. We supplement operating cash flow with debt to fund our activities as necessary. Our overall cash position reflects our business results and a global cash management strategy that takes into account liquidity management, economic factors and tax considerations.

Operating Activities

Cash provided by operating activities was $4,242, $3,711 and $2,624 in 2024, 2023 and 2022. The increase in 2024 was primarily due to higher cash earnings partially offset by changes in working capital. The increase in 2023 from 2022 was primarily due to higher net earnings and increased collections on accounts receivable.

4N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Viridian Therapeutics, Inc.

Physical Address: 221 Crescent Street, Suite 103A

City: Waltham State: MA Zip: 02453

Mailing Address (if different from physical address): 221 Crescent Street, Suite 103A

City: Waltham State: Massachusetts Zip: 02453

Telephone: 6172724600 Website: https://www.viridiantherapeutics.com/

Name of Designated Representative (DR): Kyle Haraldsen

Licensing Company Email: statelicensing@viridiantherapeutics.com DR Email: kharaldsen@viridiantherapeutics.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Prescription Drug	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors, Specialty Pharmacies		☒ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No supplies sold, dispsed or distributed within last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Publicly Traded (VRDN)

Corporation Name: Viridian Therapeutics, Inc.

Mailing Address: 221 Crescent Street, Suite 103A

City: Waltham State: Massachusetts Zip: 02453

Telephone: 6172724600 Email: statelicensing@viridiantherapeutics.com

Contact Person Name: Thomas Beetham

Date of SEC Registration: See attached	SEC Registration Number: See attached	Stock Exchange Symbol: VRDN

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Viridian Therapeutics, Inc.
Facility Name

Thomas Beetham
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/8/2025
Date

Board Use Only	Date Received: 119126	Amount: $1000-CK5750

VIRIDIAN

Description of Operations

Viridian Therapeutics, Inc. is a Virtual Manufacturer based in Massachusetts. Viridian's products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors and Specialty Pharmacies by a Third-Party Logistics Provider who is licensed to ship pharmaceutical products into your state. Viridian Therapeutics, Inc. is publicly traded on the NASDAQ (VRDN). Viridian was incorporated in the State of Delaware on 6/17/2014.

Contract Manufacturer Information:
Viridian will be using the contract manufacturer and packager below to produce our product:

WuXi Biologics Co., Ltd.
108 Meiliang Road, Mashan, Binhu District
Wuxi, Jiangsu 214092, China
FEIN: 3010606982

AndersonBrecon Inc. DBA PCI Pharma Services
4545 Assembly Drive
Rockford, IL 61109
FEIN: 1421377

At no time does Viridian's Contract Manufacturer own the product, contract with Viridian's customers, invoice, nor sell Viridian's product. Viridian's products are not Controlled Substances.

Labeler Code: 85166

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Solutions, LLC ("ICS") acts as Viridian's Third-Party Logistics (3PL) provider to manage the storage and distribution of product to Specialty Distributors and Specialty Pharmacies throughout the United States.

Integrated Commercialization Solutions, LLC
420 International Blvd., Suite 500
Brooks, KY 40109

Viridian's hours of operation are 8:00 am – 5:00pm EST Monday through Friday.



OWNERSHIP

Viridian Therapeutics, Inc is a publicly traded virtual manufacturer of pharmaceutical products located in Waltham, MA. Viridian is incorporated in the state of Delaware.

COMPANY INFORMATION

Viridian Therapeutics, Inc.
221 Crescent Street, Suite 103A
Waltham, MA 02453
Phone: 617-272-4600
statelicensing@viridiantherapeutics.com

CORPORATE OFFICERS

Thomas Beetham, Chief Operating Officer
221 Crescent Street, Suite 103A
Waltham, MA 02453

Seth Harmon, Chief Financial Officer
221 Crescent Street, Suite 103A
Waltham, MA 02453

Kyle Haraldsen, Chief Technical Operations Officer
221 Crescent Street, Suite 103A
Waltham, MA 02453

Jennifer Tousignant, Chief Legal Officer
221 Crescent Street, Suite 103A
Waltham, MA 02453

Stephen Mahoney, President & Chief Executive Officer
221 Crescent Street, Suite 103A
Waltham, MA 02453

Radhika Tripuraneni, Chief Medical Officer
221 Crescent Street, Suite 103A
Waltham, MA 02453

From: Paul Spanel
To: Paul Spanel
Subject: FW: [EXTERNAL] RE: Labeler Code Request Approved
Date: Friday, July 11, 2025 12:29:05 PM

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Tuesday, January 14, 2025 1:37 PM
To: Diane Stroehmann <dstroehmann@viridiantherapeutics.com>
Subject: Labeler Code Request Approved

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe. When in doubt, contact the IT Department

eDRLS - Electronic Drug Registration & Listing System

Current Date: 14-JAN-2025
Labeler DUNS: 063349735
Labeler Name: Viridian Therapeutics
Labeler Code Assigned: 85166

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or

processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VIRIDIAN THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF SEPTEMBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 204790833

Date: 09-18-25

4910486 8300

SR# 20254014024

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Viridian Therapeutics, Inc.
221 Crescent Street, Suite 103A
Waltham, MA 02453

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200137

Type: Virtual Manufacturer

Issue Date: 11/03/2025

Expiration Date: 11/03/2026

First Name	Last Name	Cost Centers(1)
Nadiyah	Ali	Waltham
James	Ambrose	Waltham
Thomas	Beetham	Waltham
Barbara	Bennett	Waltham
Loundja	Benseghir	Waltham
Hemlata	Bhatia	Waltham
Matthew	Birnbaum	Waltham
Kanika	Bisht	Waltham
Subhabrata	Biswas	Waltham
Shane	Bouchard	Waltham
Brette	Brickel	Waltham
Jeremy	Brinkerhoff	Waltham
Christopher	Broomell	Waltham
Cory	Burke	Waltham
Gregory	Bush	Waltham
Janice	Cardello	Waltham
Stephen	Carpenter	Waltham
Anthony	Casciano	Waltham
Lily	Cheng	Waltham
Matthew	Comeau	Waltham
Emmaline	Conti	Waltham
Debra	Danehy	Waltham
Darren	D'Augusta	Waltham
Michael	Dennis	Waltham
Kellie	DiNapoli	Waltham
Kristen	Dooley	Waltham
Elizabeth	Dorato	Waltham
Kenneth	Dungar	Waltham
Cynthia	Durkin	Waltham
Caitlin	Ferretti	Waltham
Megan	Forti	Waltham
Michael	Freibaum	Waltham

Yurong	Gao	Waltham
Amy	Gates	Waltham
Linsey	George	Waltham
Margaret	Green	Waltham
Gregory	Greene	Waltham
Sneha	Gupta	Waltham
Stephen	Gust	Waltham
Jennifer	Gyarfas	Waltham
Heather	Haley	Waltham
Kyle	Haraldsen	Waltham
Julianna	Harding	Waltham
Seth	Harmon	Waltham
Christine	Harvey	Waltham
Laura	Henao	Waltham
Robert	Hollister	Waltham
Jennifer	Hou	Waltham
Jennifer	Jacques	Waltham
Zeke	Johnston	Waltham
Deepen	Joshi	Waltham
Bijay	KC	Waltham
Mang Yin	Kwok	Waltham
Shreyas	Laghate	Waltham
Gregory	Landry	Waltham
Martha	Larence	Waltham
Yu-Lu	Ma	Waltham
Casey	Machamer	Waltham
Shauna	Mackey	Waltham
Robin	Mackowitz	Waltham
Matthew	Maguy	Waltham
Stephen	Mahoney	Waltham
Khalid	Mamlouk	Waltham
Richard	Manning	Waltham
Melissa	Manno	Waltham

Thomas	Martin	Waltham
Fabiana	Marzabal	Waltham
Jocelin	McDonough	Waltham
Tara	Mehan	Waltham
Lindsay	Merlina	Waltham
Nadezda	Mitrovic	Waltham
Elizabeth	Moessbauer	Waltham
Adrianne	Monsef	Waltham
Chad	Morin	Waltham
Carly	Morrison	Waltham
Abhijit	Narvekar	Waltham
Jasmine	Ng	Waltham
Patrick	O'Mara	Waltham
Shikha	Patel	Waltham
Harold	Pestana	Waltham
Eleonora	Presman	Waltham
Seema	Rana	Waltham
Mark	Rando	Waltham
Kathleen	Ransom	Waltham
Joseph	Raymond	Waltham
Venilde	Reis	Waltham
Ryan	Ribaudo	Waltham
Andrew	Roach	Waltham
Paulina	Roguska	Waltham
Sydney	Rosenberg	Waltham
Gregory	Rossino	Waltham
Lori	Rulli	Waltham
Kristin	Santagati	Waltham
Jon	Sarno	Waltham
Callum	Sloss	Waltham
Valerie	Smith	Waltham
Sarah	Soliman	Waltham
Elizabeth	Spingler	Waltham

Diane	Stroehmann	Waltham
Jennifer	Tousignant	Waltham
Erin	Treece	Waltham
Jordan	Tsai	Waltham
Emily	van Vliet	Waltham
Tiffanie	Veiga	Waltham
Katherine	Vight	Waltham
Jyothi	Vijayaraghavan	Waltham
Garry	Vilnits	Waltham
Christine	Waite	Waltham
Lucy	Weng	Waltham
Brian	Wiercinski	Waltham
Ireland	Williams	Waltham
Alyssa	Wiseman	Waltham
Shan	Wu	Waltham
Alyssa	Yenikomshian	Waltham
Kathy	Zagaroli	Waltham
Christian	Zdybowicz	Waltham
Xiaosha	Zhang	Waltham
Lynn	Zuchowski	Waltham

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission file number 001-36483



VIRIDIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-1187261**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

221 Crescent Street, Suite 103A, Waltham, MA 02453
(Address of principal executive offices)

Registrant's telephone number, including area code: **(617) 272-4600**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	VRDN	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based upon the closing sale price of the registrant's common stock on June 28, 2024, as reported on The Nasdaq Capital Market, was $731.8 million. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 20, 2025, there were 81,484,950 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2025 annual meeting of stockholders (the "2025 Proxy Statement") are incorporated herein by reference in Part III of this Annual Report on Form 10-K where indicated. The 2025 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2024.

VIRIDIAN THERAPEUTICS, INC.
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other results;
- the potential utility, efficacy, potency, safety, clinical benefits, half-life, clinical response, convenience and number of indications of our product candidates, including our expectation that VRDN-003 will demonstrate a similar clinical response as veligrotug;
- the timing and focus of our ongoing and future nonclinical studies and clinical trials and the timing of reporting data from those studies and trials, including that we expect to receive VRDN-006 proof of concept immunoglobulin G ("IgG") reduction data in the third quarter of 2025 and that we anticipate submitting an Investigational New Drug Application ("IND") for VRDN-008 by the end of 2025;
- supply chain disruptions, enrollment in clinical trials involving our product candidates or other delays in such trials;
- our plans relating to commercializing our product candidates, including our plans to commercialize products candidates as combination products, if approved, including the geographic areas of focus and sales strategy;
- potential market sizes and market opportunities, including the rate and degree of market acceptance and clinical utility for our product candidates;
- expectations regarding the initiation of clinical trials and interactions and alignment with regulatory authorities;
- the timing or likelihood of regulatory filings and approvals, including the anticipated biologics license application ("BLA") submission for veligrotug in the second half of 2025 and a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA") in the first half of 2026, as well as our expectation to seek an accelerated approval pathway and special designations, for our product candidates for various diseases;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- our plans to obtain or protect intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates and for the manufacture of our product candidates for nonclinical studies, clinical trials and commercialization;
- our plans regarding any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and our ability to obtain additional financing to fund our operations and complete further development and commercialization of our product candidates; and
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements.

Any forward-looking statements in this Annual Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Annual Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Annual Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission ("SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report that modify or impact any of the forward-looking statements contained in this Annual Report will be deemed to modify or supersede such statements in this Annual Report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Annual Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Unless otherwise mentioned or unless the context requires otherwise, all references in this Annual Report, to "Viridian," "Viridian Therapeutics," the "Company," "we," "us," and "our" or similar references refer to Viridian Therapeutics, Inc. and our consolidated subsidiaries.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Item 1A. Risk Factors" and should be carefully considered, together with other information in this Annual Report and our other filings with the SEC, before making an investment decision regarding our common stock.

- If we are unable to raise additional capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.
- We have historically incurred losses, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.
- Clinical trials are costly, time consuming, and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.
- Regulatory approval processes are lengthy, time-consuming and inherently unpredictable. Failure to obtain regulatory approval for our product candidates would have a material adverse effect upon our business and business prospects.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of approved labeling, or result in significant negative consequences following marketing approval, if any.
- We are heavily dependent on the success of our product candidates, which are in clinical development. Some of our product candidates have produced results only in nonclinical settings, or for other indications than those for which we contemplate conducting development and seeking U.S. Food and Drug Administration ("FDA") or other regulatory approval, and we cannot give any assurance that we will generate data for any of our product candidates sufficiently supportive to receive regulatory approval in our planned indications, which will be required before they can be commercialized.
- Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier nonclinical studies and clinical trials may not be predictive of future clinical trial results.
- We rely on third parties to conduct our nonclinical development activities and clinical trials, manufacture our product candidates, and perform other services. If these third parties do not successfully perform and/or comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval, or commercialize our product candidates and our business could be substantially harmed.
- We rely on patent rights, trade secret protections, and confidentiality agreements to protect intellectual property, including intellectual property related to our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.
- If we are unable to establish commercial manufacturing, sales and marketing capabilities or enter into agreements with third parties to commercially manufacture, market and sell our product candidates, we may be unable to generate any revenue.
- We face substantial competition and our competitors may discover, develop, or commercialize products faster or more successfully than us.
- Our future success depends in part on our ability to attract, retain, and motivate qualified personnel. If we lose key personnel, or if we fail to recruit additional highly skilled personnel, our ability to develop our product candidates will be impaired and our business may be harmed.

PART I

ITEM 1. BUSINESS

Company Overview

We are a biopharmaceutical company focused on discovering, developing, and commercializing potential best-in-class medicines for serious and rare diseases. We target disease areas where marketed therapies often leave room for improvements in efficacy, safety, and/or dosing convenience. We believe that first-generation medicines rarely represent optimal solutions, especially in rare disease areas, and that there is potential to develop differentiated, best-in-class medicines that could lead to improved patient outcomes, reduced side effects, improved quality of life, expanded market access, and augmented market competition. Our business model is designed to identify and evaluate product opportunities in disease areas where trial data establishes proof-of-concept for a drug target in the clinic, but the competitive evolution of the product life cycle management and number of entrants appears incomplete. We intend to prioritize indications where a fast-follower and a potentially differentiated drug candidate, or overall product profile, could create significant medical benefit for patients. We are engineering product candidates to address unmet medical needs for patients and further advance drug innovation.

Our goal is to identify and evaluate product concepts leveraging clinically validated molecular targets using established therapeutic modalities. We prioritize product concepts that are aligned with clinical and commercial hypotheses, which we expect will provide an attractive balance of risk and opportunity, thereby representing a compelling allocation of our resources. We focus on advancing therapeutic proteins that we either in-license or discover internally, incorporating proprietary therapeutic protein and antibody discovery and optimization platforms to advance clinical candidates with unique characteristics. We have built relevant expertise in protein and antibody discovery and engineering, biologics manufacturing, nonclinical and clinical development, and commercialization for thyroid eye disease ("TED"), development of anti-neonatal Fc receptor ("FcRn") therapies, and nonclinical and clinical development for indications in rare and autoimmune diseases.

Our approach to rapidly discovering and developing novel therapeutics relies on our scientific expertise in evaluating pre-existing clinical proof-of-concept data for the drug targets we are pursuing, and opportunities to improve upon existing investigational and/or approved therapies. This approach informs how we design, select, and develop our product candidates, including in critical areas such as pharmacokinetics, pharmacodynamics, clinical trial design, trial endpoints, and the selection and recruitment of patients. We believe this strategy reduces the risks associated with discovering and developing novel therapeutics.

Development of Therapies to Treat Thyroid Eye Disease (TED)

We are developing therapies for the treatment of TED, a serious and debilitating rare autoimmune disease that causes inflammation within the orbit of the eye that can cause bulging of the eyes, redness and swelling, double vision, pain, and potential blindness. TED significantly impacts quality of life, imposing a high burden on activities of daily living and mental health for patients suffering from the disease. TED is a progressive disease consisting of an initial active phase ("active TED"), followed by a transition to a secondary chronic phase ("chronic TED"). The only medicine approved by the FDA for TED is Tepezza® (teprotumumab), which is an intravenously administered monoclonal antibody that targets insulin-like growth factor 1 receptor ("IGF-1R"). Tepezza is marketed in the United States ("U.S.") by Horizon Therapeutics plc ("Horizon"), which was acquired by Amgen Inc. ("Amgen") in October 2023. In 2024, Amgen gained approval for Tepezza in Japan and submitted a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA").

The results from clinical trials of teprotumumab conducted by Horizon provide strong clinical validation linking the targeting of IGF-1R to clinical benefit in patients with TED. However, clinical trials evaluating teprotumumab in patients with TED reported to date used a single dosing regimen, providing little guidance as to the optimal dosing required for clinical activity in TED. We believe that there are multiple opportunities to develop fast-follower therapeutics that improve on teprotumumab's features, including dosing schedule, route of administration, and safety profile.

We are developing two product candidates, veligrotug (formerly known as VRDN-001) for intravenous ("IV") and VRDN-003 for subcutaneous ("SC") administration, to treat patients who suffer from TED. Our most advanced program, veligrotug, is a differentiated humanized monoclonal antibody targeting IGF-1R intravenously administered for the treatment of TED. In previously presented *in vitro* nonclinical data, we showed that veligrotug is a potentially differentiated full antagonist of IGF-1R, compared to teprotumumab's incomplete antagonism of IGF-1R. VRDN-003 has the same binding domain as veligrotug, and was engineered to have a longer half-life. VRDN-003 is designed to be a low-volume, infrequently-dosed subcutaneous IGF-1R for TED, which we plan to launch commercially with an auto-injector to enable at-home patient self-

administration. We believe VRDN-003 has the potential to be the best-in-class subcutaneous anti-IGF-1R product candidate by preserving the efficacy of anti-IGF-1Rs in TED, improving safety and maximizing convenience for patients.

We conducted phase 1/2 clinical trials of veligrotug in patients with active or chronic TED. In the active TED portion of the phase 1/2 clinical trials, data reported from all three dose cohorts of veligrotug (n=21) showed significant and rapid improvement in both the signs and symptoms of TED after two infusions of veligrotug compared to placebo. Across all veligrotug treated patients in the active TED trial, 71% were proptosis responders, 67% were overall responders, 62% achieved a clinical activity score ("CAS") of 0 or 1, and 54% had complete resolution of their diplopia. In the chronic TED portion of the phase 1/2 clinical trials, data reported from both dose cohorts of veligrotug (n=12) showed significant and rapid improvement in the signs and symptoms of TED after two infusions of veligrotug compared to placebo. Across all veligrotug treated patients in the chronic TED trial, 42% were proptosis responders, 40% achieved a CAS of 0 or 1, and no patients had complete resolution of their diplopia. In the phase 1/2 clinical trials of both active and chronic TED, veligrotug had a favorable safety profile and was well-tolerated by all patients treated in all dose cohorts.

We are conducting a global pivotal program for veligrotug, including evaluating its efficacy and safety in two global well-controlled phase 3 clinical trials, THRIVE and THRIVE-2, for the treatment of active and chronic TED, respectively. THRIVE and THRIVE-2 are each designed to compare a five-dose IV treatment arm of veligrotug at 10 mg/kg, dosed three weeks apart, to placebo. This five-dose veligrotug regimen features fewer infusions and a shorter time per infusion compared to teprotumumab, the currently marketed IGF-1R inhibitor. On September 10, 2024, we announced topline data from the THRIVE study, which enrolled 113 patients, randomized to veligrotug (n=75) and placebo (n=38). THRIVE achieved all primary and secondary endpoints with a high level of statistical significance ($p < 0.0001$) and was generally well-tolerated, with no treatment-related serious adverse events ("SAEs"). Veligrotug additionally showed a rapid onset of treatment effect, with the majority (53%) of veligrotug-treated patients achieving a proptosis response as early as three weeks. On December 16, 2024, we announced topline data from the THRIVE-2 study, which enrolled 188 patients, randomized to veligrotug (n=125) and placebo (n=63). THRIVE-2 achieved all primary and secondary endpoints with statistical significance and was generally well-tolerated. Veligrotug continued to demonstrate a rapid onset of treatment effect, with a statistically significant proptosis response as early as three weeks and a statistically significant reduction and resolution of diplopia as early as six weeks. THRIVE-2 is the first global phase 3 study in patients with chronic TED to demonstrate a statistically significant and clinically meaningful diplopia responder rate and rate of diplopia complete resolution. To meet the 300 patient standard safety database requirements for the veligrotug biologics license application ("BLA"), we are conducting our STRIVE clinical trial (safety database inclusive of patients from the THRIVE and THRIVE-2 trials). STRIVE is a global study of veligrotug in TED patients that utilizes broad inclusion criteria (e.g., any severity or duration of disease) and is randomized 3:1 (10 mg/kg IV with an active control of 3 mg/kg IV). In January 2025, we completed enrollment in STRIVE with a total of 231 patients, exceeding the enrollment target of 212 due to patient demand. We have also completed enrollment of the open label extension study for non-responding patients in THRIVE and THRIVE-2. We anticipate submitting a BLA for veligrotug in the second half of 2025 and an MAA to the EMA in the first half of 2026.

In addition to our intravenous veligrotug program, VRDN-003 is our subcutaneous product candidate currently in pivotal development in TED, which we selected in December 2023 following positive data in a phase 1 clinical trial in healthy volunteers.

The VRDN-003 phase 1 clinical study showed VRDN-003 to have a prolonged half-life of 40 to 50 days, which is four to five times that of veligrotug. Because of the healthy volunteer data and the similarities between the veligrotug and VRDN-003 antibodies, we expect VRDN-003 to have similar clinical responses at the exposure levels of veligrotug that led to robust clinical activity in its clinical trials to date in TED. Further, pharmacokinetic modeling of VRDN-003 based on the healthy volunteer data predicted that exposure levels of VRDN-003 could be achieved that are equivalent to exposure levels of veligrotug that produced clinically meaningful results with multiple dosing regimens of VRDN-003, i.e., subcutaneous injection every two, four, or eight weeks.

We are conducting a global pivotal program for VRDN-003, including evaluating its efficacy and safety in two global well-controlled phase 3 clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. Both studies will evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes versus placebo. Patient enrollment and dosing continues in both studies. In addition, to enable BLA submission for VRDN-003, we have initiated a safety study to meet the 300 patient standard safety database requirement (to also include patients from the REVEAL-1 and REVEAL-2 trials) and plan to initiate an auto-injector study in 2025 to enable launching VRDN-003 in an auto-injector device, if approved. We anticipate topline data for REVEAL-1 and REVEAL-2 in the first half of 2026, and we anticipate submitting a BLA for VRDN-003 for the treatment of TED by the end of 2026.

Development of FcRn Inhibitors

In addition to developing therapies for TED, we are also developing a portfolio of engineered FcRn inhibitors, including VRDN-006 and VRDN-008. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a possible significant commercial market opportunity. Our multi-pronged engineering approach has resulted in a portfolio of FcRn-targeting molecules that leverage the clinically and commercially validated mechanism of FcRn inhibition while potentially addressing the limitations of current agents such as incomplete immunoglobulin G ("IgG") suppression, safety, and inconvenience of dosing.

VRDN-006 is a highly selective Fc fragment that inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients. In non-human primate ("NHP") studies, VRDN-006 demonstrated specificity for blocking FcRn-IgG interactions while not showing decreases in albumin or increases in low-density lipoprotein ("LDL") levels, which are known potential side effects associated with certain full-length anti-FcRn monoclonal antibodies. In our head-to-head NHP studies, VRDN-006 demonstrated comparable potency and IgG reductions to efgartigimod, which is the current standard of care in FcRn inhibition, as well as a similar safety profile. We submitted an IND for VRDN-006 in December 2024, which cleared in January 2025, and we expect proof-of-concept IgG reduction data in healthy volunteers in the third quarter of 2025.

VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients. In a single, high-dose, head-to-head study in NHPs, VRDN-008 demonstrated three times the half-life of efgartigimod. Additionally, VRDN-008 showed a deeper and more sustained IgG reduction with peak IgG reductions that were 20% deeper than efgartigimod while not showing decreases in albumin or increases in LDL levels. NHP studies are ongoing to generate additional data for VRDN-008. Once completed, we plan to use the totality of VRDN-008's NHP data to build a robust pharmacokinetic and pharmacodynamic model to predict potential human dosing regimens for VRDN-008. We anticipate submitting an IND for VRDN-008 by the end of 2025.

Our Strategy

Our mission is to create and advance new biologic medicines for patients suffering from serious and rare diseases that are underserved by today's therapies. Key elements of our business strategy are to:

- **Evaluate opportunities to identify, engineer, and develop potential best-in-class therapeutic proteins and antibodies that optimize patient care.** Our pipeline of therapeutic programs represents a patient-centric model of innovation that leverages proven biology and protein and antibody technology to reduce research and development risk, while striving to address strategic gaps related to access, delivery, quality of life, efficacy, and/or safety and tolerability in targeted therapeutic areas. Our multidisciplinary search process evaluates scientific and clinical validation of therapeutic targets, market potential, and feasibility of efficiently developing a competitive product.

- **Our clinical development and commercial focus on thyroid eye disease (TED):**

  - **Seek marketing approval for veligrotug.** We are evaluating veligrotug in two pivotal global phase 3 clinical trials, THRIVE and THRIVE-2, for the treatment of active and chronic TED, respectively. THRIVE and THRIVE-2 are each designed to compare a five-dose intravenous treatment arm of veligrotug at 10 mg/kg, dosed three weeks apart, to placebo. This five-dose veligrotug regimen features fewer infusions and a shorter time per infusion compared to teprotumumab, the currently marketed IGF-1R inhibitor for TED. We reported positive topline THRIVE and THRIVE-2 data in September 2024 and December 2024, respectively. We expect that the THRIVE and THRIVE-2 phase 3 trials, together with a safety database comprising 300 treated patients (safety database inclusive of patients from the THRIVE and THRIVE-2 trials), will support global health authority registration for marketing approval in both active and chronic TED. We expect to submit a BLA for veligrotug in the second half of 2025 and an MAA to the EMA for veligrotug in the first half of 2026.

  - **Rapidly develop subcutaneous VRDN-003 as our next generation, potential best-in-class IGF-1R antibody.** VRDN-003 is designed to be self-administered subcutaneously at home as an infrequent and low-volume injection to decrease the burden on TED patients. VRDN-003 has the same binding domain as veligrotug and was engineered to have a longer half-life. VRDN-003 is designed to maintain the efficacy of IGF-1Rs as demonstrated by the marketed product, teprotumumab, and by the clinical results for veligrotug in THRIVE and THRIVE-2, while improving on its safety and maximizing patient convenience. We are evaluating VRDN-003 in two global phase 3 clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. REVEAL-1 and REVEAL-2 are each designed to evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes

versus placebo. We have initiated a safety study to meet the 300 patient standard safety database requirement (to also include patients from the REVEAL-1 and REVEAL-2 trials) and anticipate initiating an auto-injector study in 2025 to have an auto-injector device available at the time of commercial launch, if approved. We expect to report topline REVEAL-1 and REVEAL-2 data in the first half of 2026. We expect that the REVEAL-1 and REVEAL-2 phase 3 trials, together with a safety database of 300 treated patients (safety database inclusive of patients from the REVEAL-1 and REVEAL-2 trials), will support global health authority registration for marketing approval in both active and chronic TED, respectively.

- **Be a trusted partner in the care of TED patients.** We plan to cultivate a network across TED stakeholders to inform our patient-centric approach, including with patients and advocacy groups, key opinion leaders, research institutions, healthcare professionals and payers.

- **Prepare for commercialization of veligrotug and VRDN-003, for the treatment of patients with TED.** We hold worldwide commercialization rights, excluding the greater area of China, to veligrotug and VRDN-003. As a result, we have the flexibility to develop and potentially commercialize products ourselves, or alternatively to enter collaborations with industry partners.

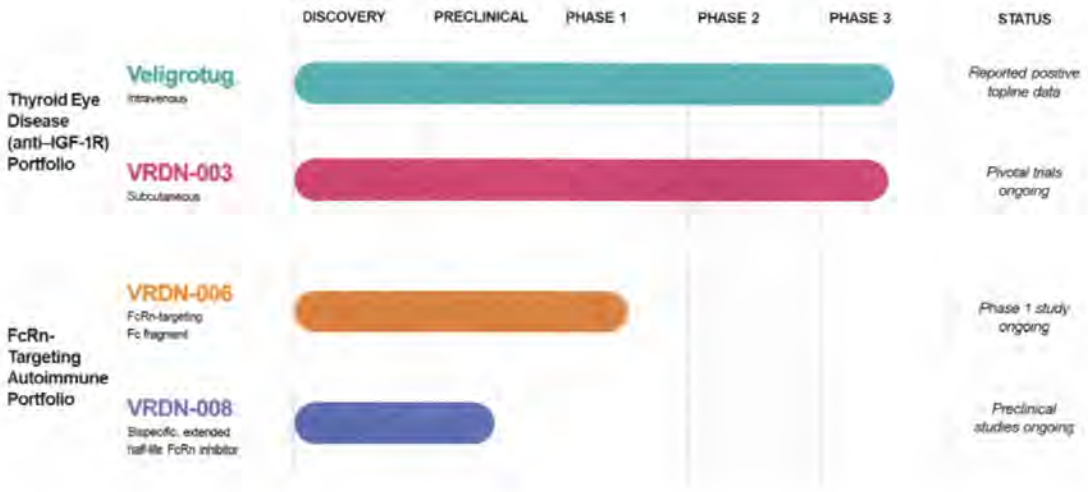
- **Advance our portfolio of FcRn inhibitors with the potential to treat a broad array of autoimmune disorders.** We are developing a portfolio of engineered anti-neonatal FcRn inhibitors, including VRDN-006 and VRDN-008. FcRn inhibitors have the potential to treat a broad array of autoimmune diseases, representing a possible significant commercial market opportunity. Our multi-pronged engineering approach has resulted in a portfolio of FcRn-targeting molecules that leverage the clinically and commercially validated mechanism of FcRn inhibition while potentially addressing the limitations of current agents such as incomplete IgG suppression and safety.

  - **Generate VRDN-006 proof-of-concept IgG reduction data in healthy volunteers.** VRDN-006 is a highly selective Fc fragment that inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients. VRDN-006 received IND clearance from the FDA in January 2025 and we expect proof-of-concept IgG reduction data in healthy volunteers in the third quarter of 2025.

  - **Advance VRDN-008 to the clinic.** VRDN-008 is a half-life extended bispecific FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression as a subcutaneous, self-administered and potential best-in-class option for patients. In single, high-dose head-to-head NHP studies, VRDN-008 demonstrated three times the half-life and showed a deeper and more sustained IgG reduction than efgartigimod. NHP studies are ongoing to generate additional data for VRDN-008. Once completed, we plan to use the totality of VRDN-008's NHP data to build a robust pharmacokinetic and pharmacodynamic model to predict potential human dosing regimens for VRDN-008. We anticipate submitting an IND for VRDN-008 by the end of 2025.

- **Leverage our therapeutic protein, antibody, and multi-disciplinary search expertise to continue discovering and developing novel, best-in class product candidates.** We plan to continue to identify and advance novel product candidates and technologies to generate potential best-in-class protein and antibody therapeutics, either internally or through in-licensing.

Our Pipeline



Thyroid Eye Disease (TED)

TED, commonly associated with Graves' Disease, and in some cases referred to as Graves' orbitopathy, is a serious and rare autoimmune disorder affecting the eye and its adjacent tissue. It is characterized by inflammation within the orbit of the eye that can cause bulging of the eyes, redness and swelling, double vision, pain, and potential blindness. TED is a progressive disease consisting of an initial active phase or active TED, followed by a transition to a secondary chronic phase or chronic TED. In the active phase of TED, patients present with several inflammatory signs and symptoms such as pain, redness, swelling, proptosis, diplopia, and eyelid retraction. The active phase is generally defined as the first 18 to 24 months of disease onset and is typically when inflammatory signs and symptoms reach their peak levels. The second, chronic phase of TED is characterized by a reduction in some of the inflammatory signs, such as redness and swelling in the area surrounding the eye, compared to the active phase of the disease. However, proptosis, pain, diplopia, and eyelid retraction often persist throughout life for patients with chronic TED. Patients with active and chronic TED experience significant impairment to their quality of life, including difficulties with the activities of daily living, trouble functioning in social situations, and decreased psychological well-being. About one in every three patients experience anxiety and depression.

Pathologies Leading to the Development of TED

TED develops in parallel with Graves' Disease, an autoimmune disease in which antibodies form against the thyroid-stimulating hormone receptor ("TSHR"), which is present in the thyroid and other cells such as adipocytes and fibroblasts. A close temporal relationship exists between the onset of Graves' Disease and the onset of TED. Regardless of which condition occurs first, the other condition develops within 18 months in 80% of patients. In addition to antibodies against TSHR, patients with TED also develop antibodies against IGF-1R.

Insulin-like growth factor 1 is a hormone similar in molecular structure to insulin with higher growth-promoting activity. IGF-1R, the receptor for IGF-1, is highly expressed in fibrocytes, cells that are derived from the bone marrow and that have the potential to differentiate into either myofibroblasts or fat cells. IGF-1R and TSHR function in concert to regulate the proliferation and differentiation of fibrocytes in the orbital socket.

One potential cause of TED is autoimmune antibodies against IGF-1R that lead to the activation of IGF-1R, resulting in increased proliferation, secretion of extracellular complex carbohydrates, and differentiation into fat cells. These antibodies, and autoimmune antibodies to TSHR, can elicit an immune attack against the fibrocytes that surround the eye triggering the

development of TED. Inflammation associated with this attack combined with activation of IGF-1R leads to the wide spectrum of pathologies seen with this disease.

Exposure to other inflammatory agents, such as cigarette smoke, leads to exacerbation of the disease resulting in more severe symptoms.

Current Treatments for TED

Prior to 2020, moderate to severe cases of TED were treated off-label with steroids such as daily doses of oral prednisone, or in more severe cases, weekly doses of IV methylprednisolone. Treatment with steroids is associated with a wide range of serious complications including high blood pressure, diabetes, psychological effects, personality change, insomnia, skin thinning, immunosuppression, hyperglycemia, and increased risks of infections. Systemic steroids showed limited efficacy for most of the signs and symptoms of TED and are not a sustainable long-range intervention given the side effects. If steroid treatment proved to be inadequate, or could not be tolerated, remaining options for patients include orbital radiation or surgery to reduce swelling, decompress orbital contents, and protect the vision. Again, each of these therapies was considered incomplete or inadequate from the perspective of both the patient and the treating physician.

In January 2020, Tepezza (teprotumumab), an antibody that blocks the activation of IGF-1R, was approved by the FDA for the treatment of TED. The Tepezza labeling was updated in April 2023 to specify its use for the treatment of TED regardless of TED activity or duration. In addition, the labeling was updated in its warnings and precautions, adverse reactions, and patient counseling information sections in December 2022 with additional information on hyperglycemia and in July 2023 to include hearing impairment, its potential severity, and guidance for monitoring.

In two randomized, double-blind placebo-controlled trials, infusions of teprotumumab every three weeks, for a total of eight doses, led to a greater than 2 mm decrease in proptosis in 71% and 83% of patients with active TED, respectively, compared to 20% and 10% with placebo. Combined results from these two studies in patients with active TED showed that treatment with teprotumumab also led to a 53% decrease in diplopia compared to a 25% decrease when patients were treated with placebo control. Thus, these data show that targeting and blockade of IGF-1R in TED provides a clinically meaningful benefit and is a de-risked approach.

Market Potential

We estimate approximately 190,000 TED patients in the United States with moderate to severe TED, which includes patients with either active and chronic TED, and a similar epidemiology in Europe. In 2020, Horizon launched with a price of approximately $16,300 per vial of Tepezza which translates to a list price of approximately $375,000 based on patient weight for a six-month course of therapy. Tepezza's 2024 net sales in the U.S. were approximately $1.8 billion, with the potential for additional revenue in the U.S. with further penetration into the prevalent TED population and more convenient regimens and routes of administration. With Tepezza now approved in multiple countries outside of the U.S., including Japan, and a regulatory submission completed in Europe, we believe there is potential for meaningful additional revenue outside of the U.S., which we believe will further support multiple entrants.

Our Product Candidates

Veligrotug, a potential best-in-class intravenously administered IGF-1R antibody

Veligrotug is a monoclonal antibody that binds to and is believed to act as a full antagonist of IGF-1R signaling pathway. This mechanism of action is clinically and commercially validated by the only FDA product approved for the treatment of TED, Tepezza. Based on our ongoing THRIVE and THRIVE-2 phase 3 clinical trials, our goal is for veligrotug to be second to market in this class of medicine, with the opportunity to offer a differentiated IV product.

We have an exclusive license to the worldwide rights to develop and commercialize veligrotug for all non-oncology indications that do not use radiopharmaceuticals, including the treatment of patients with TED, from ImmunoGen, Inc. ("ImmunoGen"). The antibody sequence that we are developing as veligrotug in TED had previously been developed in oncology as AVE-1642 and studied in over 100 patients. However, development in oncology was stopped in 2009 due to its failure to meet the primary efficacy endpoints in multiple myeloma. As described below, we sublicensed the right to develop, manufacture and commercialize certain IGF-1R directed antibody products for non-oncology indications in the greater area of China to Zenas BioPharma (Cayman) Limited (now Zenas BioPharma, Inc., their successor in interest, "Zenas BioPharma"). In January 2025, Zenas BioPharma sublicensed their rights to Zai Lab (Hong King) Limited ("Zai Lab").

Clinical Trials for veligrotug

Phase 1/2 Trial of veligrotug in Patients with Active TED

In the second half of 2022 and early 2023, we announced data from our phase 1/2 clinical trial evaluating the safety and efficacy of veligrotug in patients with active TED. The proof-of-concept portion of this double-blind, placebo-controlled phase 1/2 trial evaluated two infusions of veligrotug administered intravenously, three weeks apart, with efficacy measured six weeks after the first dose. Veligrotug was evaluated at doses of 3, 10, and 20 mg/kg, with each cohort designed to include six patients randomized to drug, and two patients randomized to placebo. We previously announced positive results from all three dose cohorts, and veligrotug demonstrated a favorable safety profile. In the 3 mg/kg dose cohort, nine patients were randomized to receive veligrotug to enable all consented patients who were eligible following screening to participate in the trial, and two patients were randomized to receive placebo. At week 6, across all three dose groups (n=21), we observed a 71% proptosis responder rate and a 67% overall responder rate. 62% of veligrotug-treated patients achieved a CAS of 0 or 1, and 54% had complete resolution of their diplopia. Veligrotug was generally well-tolerated.

Phase 1/2 Trial of veligrotug in Patients with Chronic TED

In July 2023, we announced data from our phase 1/2 clinical trial evaluating the safety and efficacy of veligrotug in patients with chronic TED. The proof-of-concept portion of this double-blind, placebo-controlled phase 1/2 trial evaluated two infusions of veligrotug administered intravenously, three weeks apart, with efficacy measured six weeks after the first dose. Veligrotug was evaluated at doses of 3 and 10 mg/kg, with each cohort designed to include six patients randomized to drug, and two patients randomized to placebo. We previously announced positive results from both cohorts, and veligrotug demonstrated a favorable safety profile that was generally consistent with the previously reported results in patients with active TED with veligrotug. At week six, across both dose groups (n=12), we observed a 42% proptosis responder rate and 40% of veligrotug-treated patients achieving a CAS of 0 or 1. No patients achieved complete resolution of their diplopia. Veligrotug was generally well-tolerated and demonstrated a safety profile that was generally consistent with the previously reported results in patients with active TED with veligrotug.

Phase 3 Trial (THRIVE) of veligrotug in Patients with Active TED

THRIVE is a global double-masked, placebo-controlled phase 3 clinical trial evaluating the safety and efficacy of veligrotug in patients with active TED. THRIVE evaluated five infusions of veligrotug at 10 mg/kg, dosed three weeks apart. Patients were randomized two to drug and one to placebo.

In September 2024, we announced positive topline data from THRIVE. THRIVE met the primary and all secondary endpoints at fifteen weeks after five infusions of veligrotug, showing highly statistically significant ($p < 0.0001$) improvements on all of the measured signs and symptoms of TED. Veligrotug additionally showed a rapid onset of treatment effect, with the majority (53%) of veligrotug-treated patients achieving a proptosis response as early as three weeks. THRIVE enrolled 113 patients, randomized to veligrotug (n=75) and placebo (n=38).

The following activity was observed in veligrotug-treated patients at week fifteen (n=75):

Proptosis

- 70% proptosis responder rate ("PRR") (64% placebo-adjusted, $p < 0.0001$), defined as a ≥2-millimeter ("mm") reduction in proptosis from baseline in the study eye without worsening in the fellow eye (≥2 mm increase), as measured by exophthalmometry. PRR results as measured by MRI/CT were consistent with those measured by exophthalmometry at the primary efficacy analysis timepoint.

- 2.9mm mean reduction in proptosis from baseline (2.4mm placebo-adjusted, $p < 0.0001$), as measured by exophthalmometry

Diplopia

- 63% diplopia responder rate (43% placebo-adjusted, $p < 0.0001$), defined as patients with baseline diplopia who achieved a reduction of at least 1 on the Gorman subjective diplopia scale (76 patients with diplopia at baseline)

- 54% complete resolution of diplopia (43% placebo-adjusted, $p < 0.0001$), defined as patients with baseline diplopia who achieved a score of 0 on the Gorman subjective diplopia scale

CAS

- 64% maximal or near-maximal therapeutic effect on CAS (46% placebo-adjusted, $p < 0.0001$), defined as reaching a CAS of 0 or 1 on the 7-point composite measure of signs and symptoms of TED
- 3.4 point mean reduction in CAS from baseline (1.7-point placebo-adjusted, $p < 0.0001$), on a 7-point measure of signs and symptoms of TED

Overall response

- 67% overall responder rate (61% placebo-adjusted, $p < 0.0001$), defined as a ≥2 mm reduction in proptosis and a ≥2 point reduction in CAS

Veligrotug was generally well-tolerated with a safety profile consistent with previous veligrotug studies. The majority of adverse events ("AEs") were mild, and 96% of veligrotug-treated patients completing all doses. There were no treatment-related serious AEs. A 5.5% placebo-adjusted rate of hearing impairment AEs was observed.

Phase 3 Trial (THRIVE-2) of veligrotug in Patients with Chronic TED

THRIVE-2 is a global double-masked, placebo-controlled phase 3 clinical trial evaluating the safety and efficacy of veligrotug in patients with chronic TED. THRIVE-2 evaluated five infusions of veligrotug at 10 mg/kg, dosed three weeks apart. Patients were randomized two to drug and one to placebo.

In December 2024, we announced positive topline data from THRIVE-2. THRIVE-2 met the primary and all secondary endpoints at fifteen weeks after five infusions of veligrotug, showing statistically significant responses on all of the measured signs and symptoms of TED. Veligrotug continued to demonstrate a rapid onset of treatment effect, with a statistically significant proptosis response as early as three weeks and statistically significant diplopia reduction and resolution as early as six weeks. THRIVE-2 is the first global phase 3 study in patients with chronic TED to demonstrate a statistically significant and clinically meaningful diplopia responder rate and rate of diplopia complete resolution. THRIVE-2 enrolled 188 patients, randomized to veligrotug (n=125) and placebo (n=63). The mean time since onset of TED in patients treated with veligrotug was 69.8 months.

The following activity was observed in veligrotug-treated patients at week fifteen (n=125):

Proptosis

- 56% proptosis responder rate ("PRR") (48% placebo-adjusted; $p < 0.0001$), defined as a ≥2-millimeter ("mm") reduction in proptosis from baseline in the study eye without worsening in the fellow eye (≥2 mm increase), as measured by exophthalmometry. PRR was statistically significant at all time points, including as early as 3 weeks, demonstrating a rapid onset of treatment effect. PRR results as measured by MRI/CT were consistent with those measured by exophthalmometry at the primary efficacy analysis timepoint.
- 2.3mm mean reduction in proptosis from baseline (1.9mm placebo-adjusted, $p < 0.0001$), as measured by exophthalmometry

Diplopia

- 56% diplopia responder rate (31% placebo-adjusted, $p = 0.0006$), defined as patients with baseline diplopia who achieved a reduction of at least 1 on the Gorman subjective diplopia scale. Rapid onset was observed as early as 6 weeks after just two infusions (102 patients with diplopia at baseline)
- 32% complete resolution of diplopia (18% placebo-adjusted, $p = 0.0152$), defined as patients with baseline diplopia who achieved a score of 0 on the Gorman subjective diplopia scale

CAS

- 54% maximal or near-maximal therapeutic effect on CAS (29% placebo-adjusted, $p = 0.006$), defined as reaching a CAS of 0 or 1 on the 7-point composite measure of signs and symptoms of TED, among patients with a CAS of ≥ 3 at baseline (n = 104)

- 2.9 point mean reduction in CAS from baseline (1.6-point placebo-adjusted, $p < 0.0001$), on a 7-point measure of signs and symptoms of TED, among patients with a CAS of ≥ 3 at baseline

- CAS outcomes are exploratory endpoints and p-values are nominally significant.

Overall response

- 56% overall responder rate (50% placebo-adjusted, $p < 0.0001$), defined as a ≥ 2 mm reduction in proptosis and a ≥ 1 point reduction in CAS

Veligrotug was generally well-tolerated with a safety profile consistent with previous veligrotug studies, including THRIVE. The majority of AEs were mild, and 94% of veligrotug-treated patients completed their treatment course. A 9.6% placebo-adjusted rate of hearing impairment AEs was observed.

To meet the 300 patient standard safety database requirements for the veligrotug BLA, we are conducting STRIVE, a global clinical study of veligrotug in TED patients that utilizes broad inclusion criteria (e.g., any severity or duration of disease) and is randomized 3:1 (10 mg/kg IV with an active control of 3 mg/kg IV). In January 2025, we completed enrollment in STRIVE with a total of 231 patients, exceeding the enrollment target of 212 due to patient demand. We also completed enrollment of patients in the open label extension study for non-responding patients in THRIVE and THRIVE-2.

Together, THRIVE and THRIVE-2 evaluated veligrotug in the largest and broadest population of active and chronic TED patients studied to date in global phase 3 clinical trials. We believe that these robust and consistent clinical efficacy and safety results, after only five infusions of veligrotug, support a differentiated product profile and the potential for veligrotug to be the IV treatment-of-choice for all forms of active and chronic TED. We expect that the THRIVE and THRIVE-2 phase 3 clinical trials, together with a safety database comprising 300 treated patients, will support global health authority registration for marketing approval in both active and chronic TED, respectively. We expect to submit a BLA in the second half of 2025 and an MAA to the EMA in the first half of 2026.

VRDN-003, a potential best-in-class subcutaneously administered IGF-1R antibody

VRDN-003 is a monoclonal antibody that acts as a full antagonist of IGF-1R. VRDN-003 utilizes the same binding domain as veligrotug and is engineered to extend its half-life, and therefore potentially enabling less frequent and more convenient dosing. VRDN-003 is designed to maintain the clinical response of veligrotug IV while significantly increasing patient convenience.

We believe a later-entrant subcutaneous therapy can convert meaningful portions of an IV market. There is precedent that subcutaneous therapies can quickly command substantial market share even when launching several years after an incumbent IV. Although we have designed VRDN-003 to have a superior dosing profile to its parent molecule, veligrotug, as well as to the currently marketed IV product, teprotumumab, market examples demonstrate that subcutaneous therapies have commanded market share even where such therapies have the same or worse dosing frequency than their IV counterparts. Further, subcutaneous offerings can also grow the overall market size for their class. We believe VRDN-003 has significant potential to capture a meaningful proportion of the IV TED market and to grow the TED market as a convenient, less-frequent, low-volume subcutaneous anti-IGF-1R antibody that patients take at home.

We are conducting a global pivotal program for VRDN-003, including evaluating its efficacy and safety in two global well-controlled phase 3 pivotal clinical trials, REVEAL-1 and REVEAL-2, for the treatment of active and chronic TED, respectively. We selected VRDN-003 for pivotal development in TED following positive data in a phase 1 clinical trial in healthy volunteers. This study showed VRDN-003 to have a prolonged half-life of 40 to 50 days, which is four to five times that of its parent molecule, veligrotug. Because of the similarities of veligrotug and VRDN-003, we expect VRDN-003 to have similar clinical responses at the exposure levels of veligrotug that led to robust clinical activity in its phase 2 clinical study in TED. Further, pharmacokinetic modeling of VRDN-003 predicted that exposure levels of VRDN-003 could be achieved that are equivalent to exposure levels of veligrotug that produced clinically meaningful results with multiple dosing regimens of VRDN-003, i.e., subcutaneous injection every two, four, or eight weeks. Patient enrollment and dosing continues in both REVEAL-1 and REVEAL-2. Both studies will evaluate subcutaneous VRDN-003 administered every four weeks or every eight weeks and will assess outcomes versus placebo. We expect that the REVEAL-1 and REVEAL-2 phase 3 trials, together with a safety database of 300 patients (safety database inclusive of patients from the REVEAL-1 and REVEAL-2 trials), will support global health authority registration for marketing approval in both active and chronic TED, respectively. We also anticipate initiating an auto-injector study in 2025 to have an auto-injector device available at the time of commercial launch, if approved. We anticipate topline data for REVEAL-1 and REVEAL-2 in the first half of 2026, and we anticipate submitting a BLA for VRDN-003 for the treatment of TED by the end of 2026.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located? Michigan		■ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☒ Ownership Change* ■ Name Change* ■ Location Change* (in-state only)	* If making a change, provide current license number: WH 03693	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ■ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: J&B Medical Supply Co., Inc

Physical Address: 50496 Pontiac Trail

City: Wixom State: MI Zip: 48393

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 800-737-0045 Website: https://www.jandbmedical.com

Name of Designated Representative (DR): Shawn Napora

Licensing Company Email: credentialing@jandbmedical.com DR Email: redentialing@jandbmedical.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☒ Dangerous Drugs	■ Manufacturer
☒ Practitioners	■ Controlled Substances	■ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	■ Reverse Distributor
■ Wholesalers	☒ Others: enteral, ostomy, BGM, CGM, wound care, nutritional	☒ Warehouse
☒ Veterinarians		■ Retail pharmacy wholesale distributor
☒ Others: EMT/EMS, jails, health care facilities		■ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Amerisource
Address: 1 West First Avenue City: Conshohocken State: PA Zip: 19428

Name: Mckesson
Address: 6555 State Hwy 161 City: Irving State: TX Zip: 75039

Name: Abbot
Address: 1360 South Loop Road City: Alameda State: CA Zip: 94502

Name: Tandem Diabetes
Address: 12400 High Bluff Drive City: San Diego State: CA Zip: 92130

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Michigan
Parent Company (if any): JBM JMS Holdco, Inc.
Corporation/Organization Name: J&B Medical Supply Co., Inc
Mailing Address: 50496 Pontiac Trail
City: Wixom State: MI Zip: 48393
Telephone: 800-737-0045 Email: credentialing@jandbmedical.com
Contact Person Name: David Waterman

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** 100% shares are owned by JBM JMS Holdco, Inc.		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ 100% shares are owned by JBM JMS Holdco, Inc.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** N/A	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [4]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [4]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

J&B Medical Supply Co., Inc

Facility Name

Mary Shaya

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/14/2025

Date

Board Use Only	Date Received: 8/26/25	Amount: 1000-CK-632119

August, 2025

Re: Notice of Corporate Reorganization of J&B Medical Supply Co., Inc.

To Whom it May Concern:

Please accept this letter as notice that, effective April 29, 2025 ("Effective Date"), J&B Medical Supply Co., Inc. ("J&B Medical"), which is licensed in the State of Michigan as a Wholesale Distributor, License No. 5306007104, underwent a corporate reorganization that involved inserting a holding company between J&B Medical and its beneficial owners.

Prior to the reorganization, Mary E. Shaya Living Trust, dated November 28, 1994, directly owned 51% of the equity in J&B Medical and Fawzi B. Shaya Living Trust, dated November 28, 1994, directly owned 49% of J&B Medical. To accomplish the reorganization, Mary E. Shaya Living Trust and Fawzi B. Shaya Living Trust organized a new company, JBM JMS Holdco, Inc. ("JMS Holdco"), and each transferred their equity in J&B Medical to JMS Holdco in exchange for an equivalent amount of ownership in JMS Holdco. JMS Holdco is a Michigan corporation with an address of 50496 Pontiac Trail, Wixom, MI 48393. JMS Holdco's tax identification number is 33-4652298.

After the reorganization:

- J&B Medical continues to hold the state license as a corporate entity and the tax identification number of J&B Medical remains the same (38-3271174). The operations and personnel of J&B Medical also remain the same.
- JMS Holdco owns 100% of the equity in J&B Medical.
- Mary E. Shaya Living Trust owns 51 % and Fawzi B. Shaya Living Trust owns 49% of JMS Holdco, respectively. Accordingly, the beneficial ownership and control of J&B Medical remains the same as it did before the reorganization. The tax identification numbers of Mary E. Shaya Living Trust (* * *-6591) and Fawzi B. Shaya Living Trust (85-6792505) also remain the same.

If you have any questions regarding the reorganization, please do not hesitate to contact us at credentialing@jandbmedical.com

Sincerely,

J&B Medical Supply Co., Inc.

From: Liliana Bright JBRx
Sent: Tuesday, November 4, 2025 2:12 PM
To: 'Maria Herrera' <m.herrera@pharmacy.nv.gov>
Subject: RE: Out of State change of ownership application for wholesale distributor license WH03693 for J&B Medical Supply Co., Inc

Hello Maria;

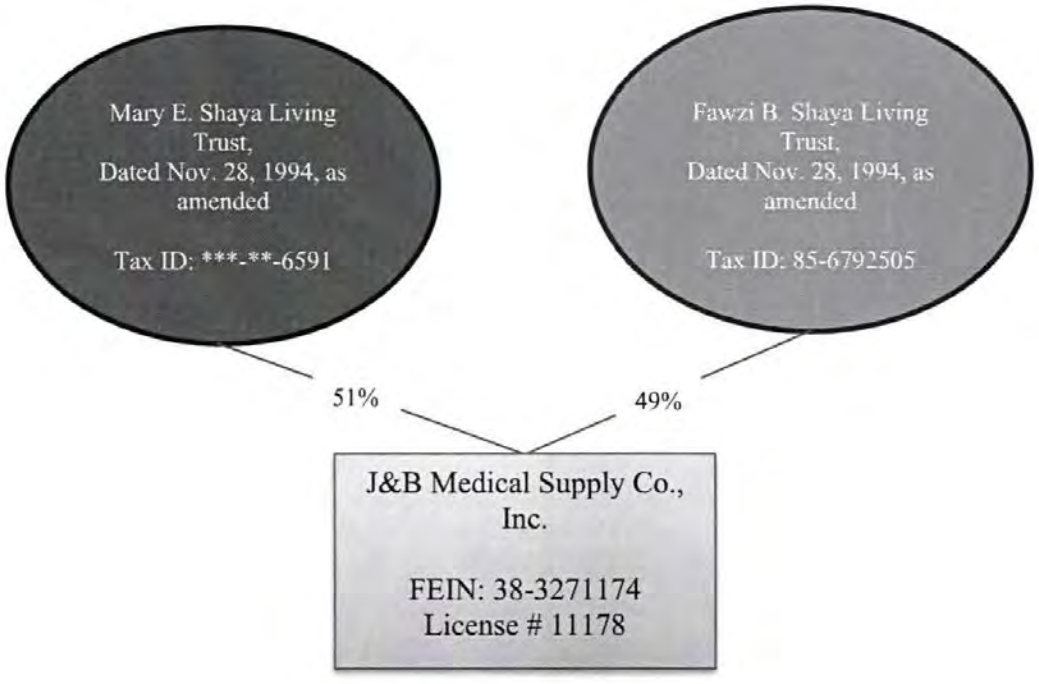
Thanks for your email.

Mrs. Mary Shaya controls the Fawzi B Shaya Living Trust. I submitted her Personal History form
Attached is a list of the main employees of the facility
Attached is the new Liability insurance

Thanks again for your time and patience.
Sincerely,
Liliana Bright
credentialing@jandbmedical.com

J&B MEDICAL SUPPLY CO.

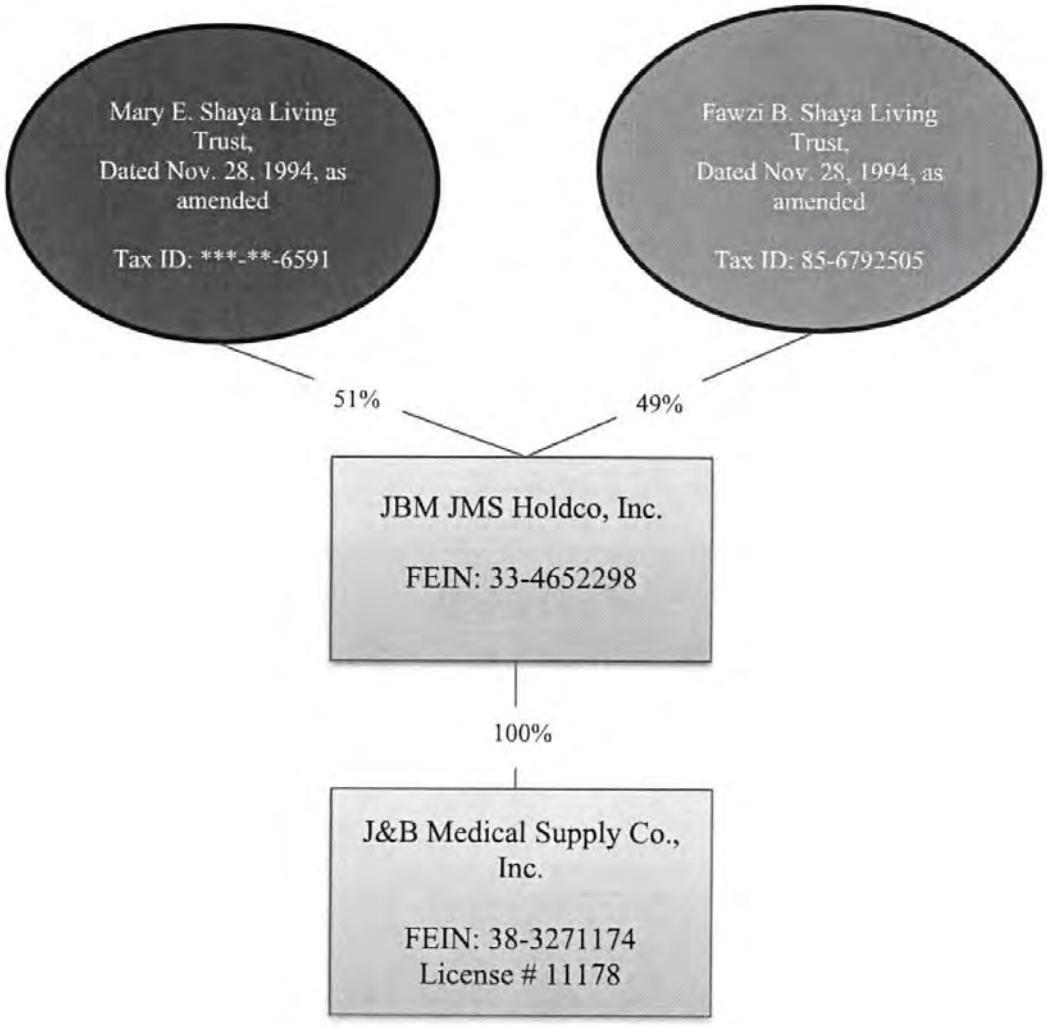
PRE-REORGANIZATION OWNERSHIP STRUCTURE



61596927.1

J&B MEDICAL SUPPLY CO.

POST-REORGANIZATION OWNERSHIP STRUCTURE
EFFECTIVE APRIL 29, 2025



NABP ACCREDITED
DRUG DISTRIBUTOR

J&B Medical Supply Co Inc

located at

50496 Pontiac Trl, Wixom, MI 48393

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

09/09/2024 - 09/08/2027
Period of Accreditation

0572

NABP ACCREDITED

OTC MEDICAL DEVICE DISTRIBUTOR

J&B Medical Supply Co Inc

located at

50496 Pontiac Trl, Wixom, MI 48393

This business has met all the OTC medical device distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the device distributor section on the NABP website, located at: www.nabp.pharmacy/programs/medical-device-distributor.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

09/09/2024 - 09/08/2027

Period of Accreditation

0573

J&B Medical Supply Co., Inc.

50496 Pontiac Trail
Wixom, MI. 48393

State of Incorporation: Michigan

FEIN: 38-3271174

Officers and Directors

Mary Shaya - President/CEO
50496 Pontiac Trail
Wixom, MI. 48393

Charlene Shaya - Executive VP
50496 Pontiac Trail
Wixom, Ml. 48393

Julian Shaya-Executive VP
50496 Pontiac Trail
Wixom, MI. 48393

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to certify:

Entity Name: J&B MEDICAL SUPPLY CO., INC.
Entity ID#: 800375685
Entity Type: Domestic Profit Corporation
Initial Filing Date: 01/12/1996
Delayed Effective Date:
Formation Jurisdiction: Michigan
Act Formed Under: 284-1972 Business Corporation Act

That the above referenced entity was validly incorporated and said corporation is validly in existence under the laws of this state.

This certificate is issued in conformity with the Act it is formed under, to attest to the fact that the company is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau
TUEBOR
CIRCUMSPICE

In testimony whereof, I have hereunto set my hand, in the City of Lansing, on November 20, 2025.

Linda Clegg

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

Certificate Number: 38053
Verify this certificate at: www.michigan.gov/corpverifycertificate

5306007104APP22

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
P.O. BOX 30670
LANSING, MI 48909

J&B MEDICAL SUPPLY CO., INC.
50496 PONTIAC TRAIL
WIXOM, MI 48393

COMPLAINT INFORMATION:
THE ISSUANCE OF THIS LICENSE SHOULD NOT BE CONSTRUED AS A WAIVER, DISMISSAL OR ACQUIESCENCE TO ANY COMPLAINTS OR VIOLATIONS PENDING AGAINST THE LICENSEE, ITS AGENTS OR EMPLOYEES.

FUTURE CONTACTS:
YOU SHOULD DIRECT INQUIRIES REGARDING THIS LICENSE OR ADDRESS CHANGES TO THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS BY EMAILING BPLHELP@MICHIGAN.GOV OR CALL (517) 241-0199

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

R083811

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR LICENSE

J&B MEDICAL SUPPLY CO., INC.
50496 PONTIAC TRAIL
WIXOM, MI 48393

LICENSE NO.
5306007104

EXPIRATION DATE
12/14/2026

24261040901

THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF MICHIGAN

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 9/30/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Carrico Maldegen Insurance 41000 West 7 Mile Road Suite 140 Northville MI 48167	**CONTACT NAME:** **PHONE (A/C, No, Ext):** 248-773-7930 **FAX (A/C, No):** 248-773-7936 **E-MAIL ADDRESS:** cmia@carricomaldegen.com
INSURED J&BMEDI-01 J & B Medical Supply Co., Inc 50496 W Pontiac Trl Wixom MI 48393	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Massachusetts Bay Insurance Co — 22306 **INSURER B :** Citizens Insurance Company of — 31534 **INSURER C :** Allmerica Financial Alliance I — 10212 **INSURER D :** Chubb Insurance Group — 41386 **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** 993838505 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			LDBD730020	10/22/2024	10/22/2025	EACH OCCURRENCE	$ 3,000,000
	[ ] CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Prof. Liability						MED EXP (Any one person)	$ 10,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$ 3,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						GENERAL AGGREGATE	$ 3,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$ 3,000,000
							Emp. Benefits	$ 1,000,000
B	AUTOMOBILE LIABILITY			A7B8119408	10/22/2024	10/22/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB [X] OCCUR			UHB-J544939	10/22/2024	10/22/2025	EACH OCCURRENCE	$ 7,000,000
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$ 7,000,000
	DED X RETENTION $ 0							$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WKB2097836	10/22/2024	10/22/2025	X PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [Y] (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$ 500,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 500,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000
D	Crime			J06655609	5/13/2024	5/13/2025	Employee Dishonesty Deductible	$5,000,000 $15,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

50496 W Pontiac Trail, Wixom MI 48393 Corporate Headquarters Warehouse. Evidence of Insurance - Property Coverage provided by B) Citizens Insurance RBH2097796, Blanket building Limit $10,755,212, Blanket Contents Limit. $15,131,000, Blanket Business Income $34,000,000.

CERTIFICATE HOLDER

J&B Medical Supply Co. Inc
50496 W Pontiac Trail
Wixom MI 48393

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/15/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Carrico Maldegen Insurance 41000 West 7 Mile Road Suite 140 Northville MI 48167	CONTACT NAME: PHONE (A/C, No, Ext): 248-773-7930 FAX (A/C, No): 248-773-7936 E-MAIL ADDRESS: cmia@carricomaldegen.com
INSURED J&BMEDI-01 J & B Medical Supply Co., Inc 50496 W Pontiac Trl Wixom MI 48393	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Massachusetts Bay Insurance Co — 22306 INSURER B : Citizens Insurance Company of — 31534 INSURER C : Allmerica Financial Alliance I — 10212 INSURER D : Chubb Insurance Group — 41386 INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 95492413 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR X Prof. Liability GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:	Y		LDBD730020	10/22/2025	10/22/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Emp. Benefits	$ 3,000,000 $ 100,000 $ 10,000 $ 3,000,000 $ 3,000,000 $ 3,000,000 $ 1,000,000
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS X HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			A7B8119408	10/22/2025	10/22/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $ $
B	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $ 0	Y		UHB-J544939	10/22/2025	10/22/2026	EACH OCCURRENCE AGGREGATE	$ 7,000,000 $ 7,000,000 $
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [Y] N/A If yes, describe under DESCRIPTION OF OPERATIONS below			WKB2097836	10/22/2025	10/22/2026	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 500,000 $ 500,000 $ 500,000
D	Crime			J06655609	5/13/2025	10/22/2026	Employee Dishonesty Deductible	$5,000,000 $15,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: State Contract#230000000346 State of Michigan, it's departments, divisions, agencies, offices, commissions, officers, employees and agents are named as additional insured with respect to General Liability as required by written contract for work performed by Named Insured and per the insurance policy provisions.

CERTIFICATE HOLDER

State of Michigan
Department of Management & Budget
Purchasing Operations
525W Allegan Street
Lansing MI 48933

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. B150043668

Application/License No. _____

Mary E. Shaya (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 50496 Pontiac Trl, Wixom, MI 48393-2088 (Address of Applicant/Principal), as PRINCIPAL, and Old Republic Surety Company (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 18500 W Corporate Dr, Ste 170, Brookfield, WI 53045 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 3/18/2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of March, 20 24.

APPLICANT/PRINCIPAL

COMPANY
Mary E. Shaya

Authorized Representative

SURETY

Old Republic Surety Company

Surety Company's Representative

Barry W. Berman, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint: Anne Solomko Of NOVI, Michigan

its true and lawful Attorney(s)-in-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, asbestos abatement contract bonds, waste management bonds, hazardous waste remediation bonds or black lung bonds),*** as follows: Effective Date of Change: 03/18/2024

Bond Number: B150043668 Bond Amount: One Hundred Thousand Dollars $ 100,000.00
Principal Name: Mary E. Shaya
Obligee Name: NV State Board of Pharmacy, Nevada

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-in-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 26th day of March, 2024.

OLD REPUBLIC SURETY COMPANY

Karen J. Haffner
Assistant Secretary

Alan Pavlic
President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 26th day of March, 2024, personally came before me, Alan Pavlic and Karen J. Haffner, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

Kathryn R. Pearson
Notary Public

My Commission Expires: 09/28/2026
(Expiration of notary's commission does not invalidate this instrument)

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0465186

Signed and sealed at the City of Brookfield, WI this 26th day of March, 2024.

Karen J. Haffner
Assistant Secretary

ORSC 22282 (3-06)

CONST BONDING SPECIALISTS LLC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG J&B Medical Supply Co., Inc MDEG License # (if applicable) _____

Physical Address 50496 Pontiac Trail

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-737-0045 Website www.jandbmedical.com

Licensing Company Email credentialing@jandbmedical.com

Section 2: Personal Information

First Shawn Middle M Last Napora

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State MI Zip [redacted]

Telephone 800-737-0045 Email credentialing@jandbmedical.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cambridge A.E		3/96-3/96	
Address	**City**	**State**	**Zip**
28522 Cambridge St	Garden City	MI	48135
Diploma/Degree obtained, if any			
G.E.D			

School Name		From - To (MM/YY – MM/YY)	
Chadsey High School		09/92-06/95	
Address	**City**	**State**	**Zip**
5335 Martin St	Detroit	MI	48210
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/06-present	[redacted]	[redacted]	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
J&B Medical Supply Co., Inc			06/20-present	
Business Address		City	State	Zip
50496 Pontiac Trail		Wixom	MI	48393
Phone	Title		Number of Employed Hours	
800-737-0045	Warehouse Supervisor		7360+	
Description of Duties				
Managment of all warehouse employees and daily activities and operations of the warehouse. Control of inventory, inbound, outbound. Enforcing of policies and procedures.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

J. M. M. — 8/19/25

Original Signature (electronic, copies or stamps not accepted) — Date

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

I, Shawn M Napora, **certify that as the MDEG Administrator for**

J&B Medical Supply Co., Inc,

that I (initial that you have read and meet the following requirements):

1. SMN Have a high school diploma or its equivalent;
2. SMN Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SMN Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SMN Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shawn M Napora
Print Name (First, Last)

S. M. N.
Original Signature (electronic, copies or stamps not accepted)

8/19/25
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler J&B Medical Supply Co., Inc.

Physical Address 50496 Pontiac Trail

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-737-0045 Website https://www.jandbmedical.com

Licensing Company Email credentialing@jandbmedical.com

Section 2: Personal Information

First Shawn Middle M Last Napora

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State MI Zip [redacted]

Telephone [redacted] Email Snapora@jandbmedical.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: 10/27/1999 to: 10/27/2003

Military Occupation/Specialty Chemical,Biological and Radio-logical Defense specialist.

Branch: ☐ Army/Reserves ■ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials SMN

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cambridge A.E.		03/96-03/96	
Address	**City**	**State**	**Zip**
28522 Cambridge st.	Garden City	MI	48135
Diploma/Degree obtained, if any			
G.E.D			

School Name		From - To (MM/YY – MM/YY)	
Chadsey High School		09/92-06/95	
Address	**City**	**State**	**Zip**
5335 Martin st.	Detroit	MI	48210
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/06-Present	[redacted]	[redacted]	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials SMN

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: J&B Medical Supply Co. Inc.			From - To (MM/YY – MM/YY): 06/20-Present
Business Address: 50496 Pontiac Trail	City: Wixom	State: MI	Zip: 48393
Phone: (800) 737-0045	Title: Warehouse Supervisor		Number of Employed Hours: 7360+
Description of Duties: Management of all warehouse employee's and Safety policies. Control of warehouse inventory inbound and outbound.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Shawn Napora, **certify that as the designated representative for**

J&B Medical Supply Co., Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SN I am at least 21 years of age;
3. SN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Shawn Napora

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/19/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shawn Napora

Print Name (First, Last)

S. M. N. 8/19/25

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Oakland

I, SHAWN M. NAPORA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

S. M. N. 8/19/25

Original Signature **Date**

Subscribed and Sworn to before me this 19 day of August 2025.

Cynthia R. Hughes

Notary Public Signature

CYNTHIA RENEE HUGHES
NOTARY PUBLIC, STATE OF MI
COUNTY OF LIVINGSTON
MY COMMISSION EXPIRES Dec 3, 2030
ACTING IN COUNTY OF Oakland

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site J&B Medical Supply Co., Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH03693

Physical Address 50496 Pontiac Trail

City Wixom State MI Zip 48393

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 800-737-0045 Website jandbmedical.com

Licensing Company Email credentialing@jandbmedical.com

Section 2: Personal Information

First Mary Middle _____ Last Shaya

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State MI Zip [redacted]

Telephone 800-737-0045 Email credentialing@jandbmedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Cooley High School (closed)			1966 - 1969	
Address		City	State	Zip
15055 Hubbell Ave		Detroit	MI	48227
Diploma/Degree obtained, if any				
Graduated with Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2012-present	[redacted]	[redacted]	MI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
J&B Medical Supply Co., Inc.			1994-present
Business Address	**City**	**State**	**Zip**
50496 Pontiac Trai	Wixom	MI	48393
Phone	**Title**		
800-737--0045	President-Owner		

Description of Duties

Leadership and development of corporate structure, maintains everyday business overview, initiates company policy, responsible for management and organization of over 100 employees, controls financial transactions.

Business Name			From - To (MM/YY – MM/YY)
Labcorp			1998-2003
Business Address	**City**	**State**	**Zip**
N/A			
Phone	**Title**		

Description of Duties

Managed and directed several sales reps, trained new hires in sales, monitored sales accounts, created procedures for maintaining vendor relationships.

Business Name			From - To (MM/YY – MM/YY)
Universal Standard			1993-1998
Business Address	**City**	**State**	**Zip**
N/A			
Phone	**Title**		

Description of Duties

Conducted business-to-business sales representing multiple product lines, established new customer base, generated sales leads, trained/mentored new reps.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mary Shaya

Print Name (First, Last)

Mary E Shaya

Original Signature (electronic, copies or stamps not accepted)

10-23-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Michigan, ss. County of Oakland

I, Mary Shaya, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Mary E Shaya

Original Signature

10-23-2025

Date

Subscribed and Sworn to before me this 23rd day of October.

Cynthia Hughes

Notary Public Signature

CYNTHIA RENEE HUGHES
NOTARY PUBLIC, STATE OF MI
COUNTY OF LIVINGSTON
MY COMMISSION EXPIRES Dec 3, 2030
ACTING IN COUNTY OF Oakland

(Seal)

J&B MEDICAL
50496 Pontiac Trail • Wixom, MI 48393 • **Phone:** (800) 737-0045 • **Fax:** (800) 737-0012

J&B Medical Supply Co., Inc

Eric Karrumi- Warehouse Manager

Nick Orosey- Maintenance Manager

John Stalker- Warehouse Supervisor

Marco Centeno- Warehouse Supervisor

Angela Moreira- Warehouse Supervisor

Shawn Napora- Warehouse Supervisor

Malina Burgess- Warehouse Team Lead

Mark Banister- Warehouse Team Lead

Daniel Banister- Warehouse Team Lead

Richard Kendra- Warehouse Team Lead

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02270	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Optime Care Inc.

Physical Address: 4064 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 314-731-6900 Website: www.optimecare.com

Name of Designated Representative (DR): Amy Kern

Licensing Company Email: licensing@optimecare.com DR Email: amy.kern@optimecare.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/19/2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Eton Pharmaceuticals Inc
Address: 21925 W Field Pkwy, Ste 235 City: Deer Park State: IL Zip: 60010

Name: BioCryst Pharmaceuticals
Address: 4505 Emperor Blvd, Ste 200 City: Durham State: NC Zip: 27703

Name: Corcept Therapeutics
Address: 101 Redwood Shores Pkwy City: Redwood City State: CA Zip: 94065

Name: Immunocore
Address: 181 Washington Street, STE 200 City: Conshohocken State: PA Zip: 19428

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Innovative Specialty Solutions, LLC
Corporation/Organization Name: Optime Care Inc.
Mailing Address: 4060 Wedgeway Ct.
City: Earth City State: MO Zip: 63045
Telephone: 314-731-6900 Email: licensing@optimecare.com
Contact Person Name: Jennifer Keyser

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Optime Care Inc.

Facility Name

Bill Oldham

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10-2-25

Date

Board Use Only	Date Received: 12/11/25	Amount: $1000 CK 6015

NABP ACCREDITED
DRUG DISTRIBUTOR

Optime Care Inc

located at

4064 Wedgeway Ct, Earth City, MO 63045

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

10/30/2023 - 10/29/2026
Period of Accreditation

0608

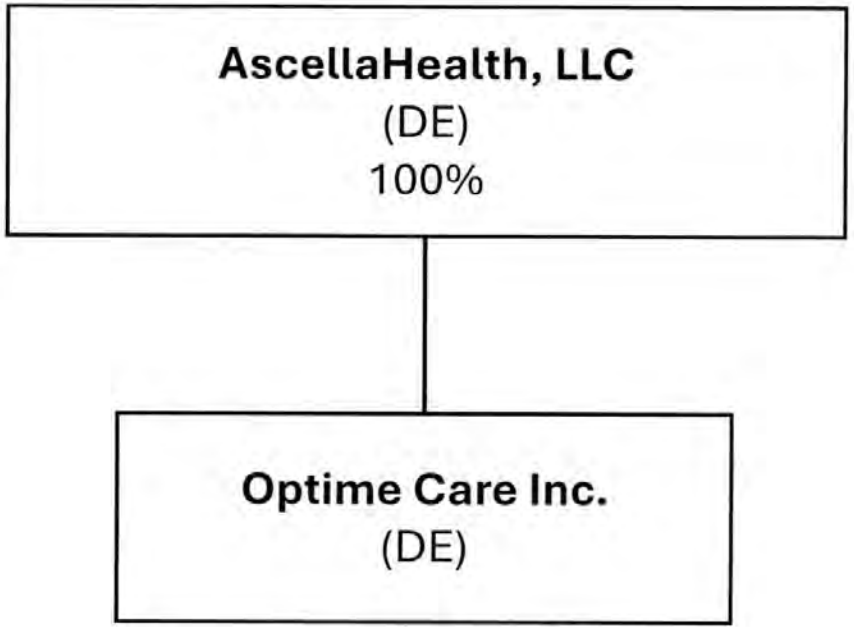


Owner of Optime Care Inc.:
Innovative Specialty Solutions, LLC (Parent Company)
1055 Westlakes Drive
Suite 200
Berwyn, PA 19312
FEIN: 93-3985400
100% Owner

Officers Optime Care Inc.:
Dea Belazi, Director
1055 Westlakes Drive
Suite 200
Berwyn, PA 19312
Phone: 877-389-9040

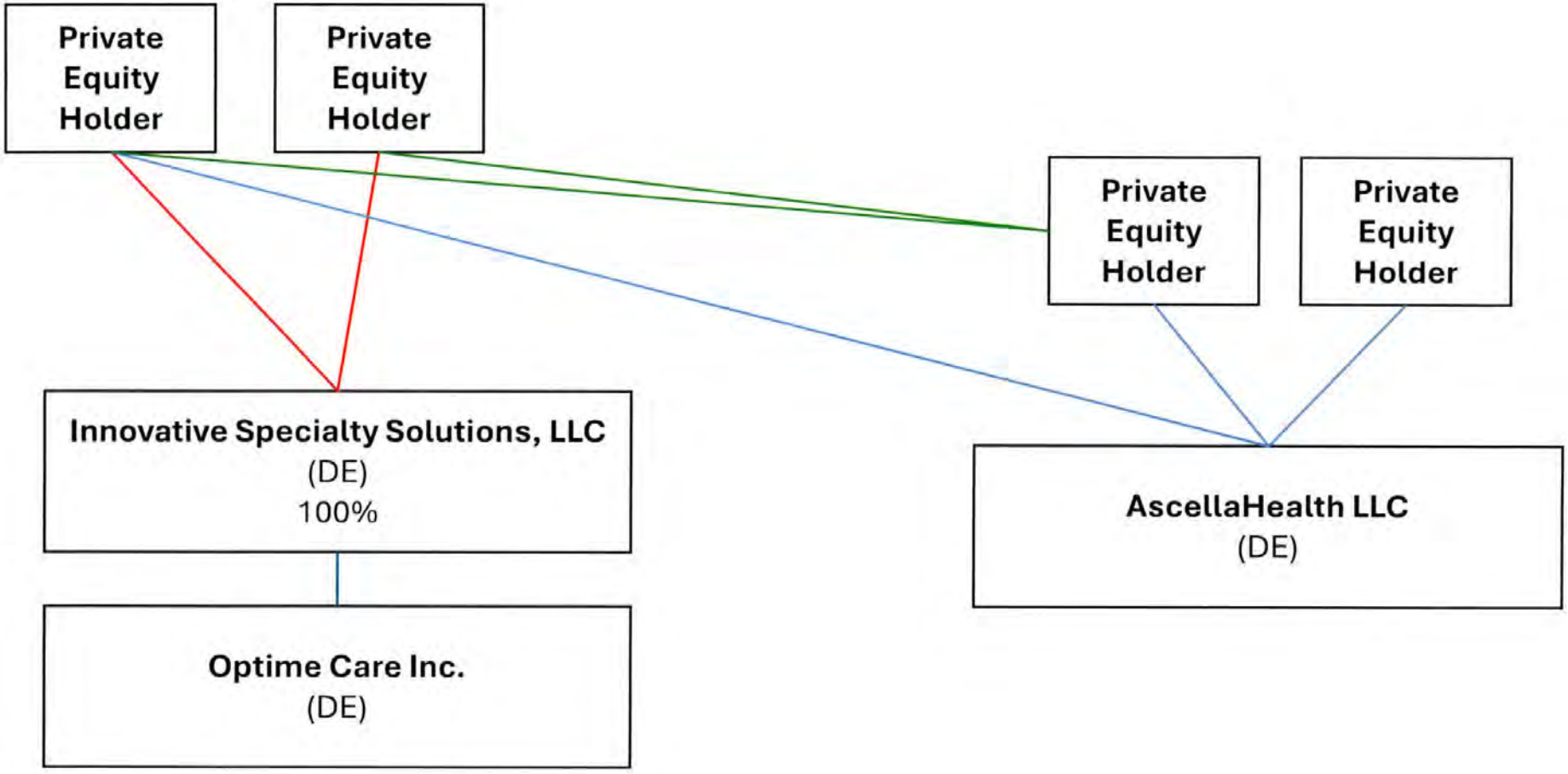
Bill Oldham, President
1055 Westlakes Drive
Suite 200
Berwyn, PA 19312
Phone: 877-389-9040

Optime Care Inc.
Pre-Restructure Organization Structure



Effective December 15, 2021

Post-Restructure Organization Chart



CONFIDENTIAL – NOT FOR DISTRIBUTION

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OPTIME CARE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF JUNE, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "OPTIME CARE INC." WAS INCORPORATED ON THE SEVENTH DAY OF AUGUST, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5800132 8300

SR# 20252962925

Authentication: 203861250

Date: 06-04-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Missouri
Division of Professional Registration
Drug Distributor

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2025017663
OPTIME CARE INC.
OPTIME CARE INC.
4064 WEDGEWAY COURT
EARTH CITY MO 63045
UNITED STATES

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Drug Distributor

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2025017663
Amy Kern

OPTIME CARE INC.
OPTIME CARE INC.
4064 WEDGEWAY COURT
EARTH CITY MO 63045
UNITED STATES

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

Liberty Mutual SURETY

CONTINUATION CERTIFICATE

The Ohio Casualty Insurance Company Surety upon:

a certain Bond No.: **39S211924**

Cross Ref Bond No.:

dated effective: September 7, 2016

on behalf of: Optime Care, Inc.

and in favor of: State of Nevada

does hereby continue said bond in force for the further period:

beginning on: September 7, 2025

and ending on: September 7, 2026

Amount of bond: $100,000.00

Description of bond: Pharmaceutical Wholesaler Surety Bond

PROVIDED: That this continuation certificate does not create a new obligation and is executed upon the express condition and provision that the Surety's liability under said bond and this and all Continuation Certificates issued in connection therewith shall not be cumulative and that the said Surety's aggregate liability under said bond and this and all such Continuation Certificates on account of all defaults committed during the period (regardless of the number of years) said bond had been and shall be in force, shall not in any event exceed the amount of said bond as hereinbefore set forth.

Signed and dated on: September 10, 2025

Surety Name: The Ohio Casualty Insurance Company

THE OHIO CASUALTY INSURANCE COMPANY INCORPORATED 1919 NEW HAMPSHIRE

By: Timothy A. Mikolajewski

Timothy A. Mikolajewski, Assistant Secretary

Agency Name: WH Missouri LLC

Agency Address: 580 Old State Rd, Ellisville, MO 63021

Agency Telephone: 314-384-2923

POWER OF ATTORNEY

The Ohio Casualty Insurance Company

Principal: Optime Care, Inc.
Agency Name: WH Missouri LLC Bond Number: 398211924
Obligee: State of Nevada
Bond Amount: ($100,000.00) One Hundred Thousand Dollars And Zero Cents

KNOW ALL PERSONS BY THESE PRESENTS: that The Ohio Casualty Insurance Company, a corporation duly organized under the laws of the State of New Hampshire (herein collectively called the "Company"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint **Timothy A. Mikolajewski** in the city and state of **Seattle, WA**, each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Company in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Company and the corporate seal of the Company has been affixed thereto this 10th day of September, 2025.

The Ohio Casualty Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA
COUNTY OF MONTGOMERY ss

On this 10th day of September, 2025, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of The Ohio Casualty Insurance Company and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-law and Authorizations of The Ohio Casualty Insurance Company, which is now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature or electronic signatures of any assistant secretary of the Company or facsimile or mechanically reproduced or electronic seal of the Company, wherever appearing upon a certified copy of any power of attorney or bond issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of The Ohio Casualty Insurance Company do hereby certify that this power of attorney executed by said Company is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Company this 10th day of September, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual SURETY

St. Louis
12444 Powerscourt Drive
Saint Louis, Missouri 63131
+1 (888) 8480860 Fax: +1 (866) 5484962

Report of Renewal

Registered: July 16, 2020
Market Segment: LSF Commercial
Producer Name: JOSEPH SIMOKAITIS
Agency Code: 969939

Principal:
Optime Care, Inc.
4060 & 4064 Wedgeway Ct.
Earth City, Missouri 63045

Account:
Optime Care, Inc.
4060 & 4064 Wedgeway Ct.
Earth City, Missouri 63045

Agency:
INDEPENDENT BROKERS AGENCY LLC
950 FRANCIS PLACE STE 316
CLAYTON, Missouri 63105-2465

Invoiced to:
Optime Care, Inc.
Attn: Cindy Hohn
Optime Care, Inc.
4060 Wedgeway Ct.
Earth City, Missouri 63045

LMS Bond Number: 39S211924

Cross Reference:

Obligee:
State of Nevada
431 W Plumb Lane
Reno, Nevada 89509

Additional Obligees:

Bond Period: 9/7/2020 to 9/7/2021
Cancellation Provision: 30 Days
Company: The Ohio Casualty Insurance Company
Bond Amount: 100,000.00 USD

Transaction Eff. Date: 9/7/2020
Premium Period: 9/7/2020 to 9/7/2021
Renewal Type: Renew By Certificate
Class Code: 579
Co-surety:

Bond Description:
Pharmaceutical Wholesaler Surety Bond

Transaction Comments:

Amt in USD

Bond Premium:
2,000.00

Net Premium: 2,000.00

User: D . Boy
Printed: 09/03/2020

Liberty Mutual Surety

National Bond Ctr
310 E. 96th Street
Indianapolis, IN 46240
888-844-2663 Fax: 866-547-4883

INDEPENDENT BROKERS AGENCY LLC
950 FRANCIS PLACE STE 316
CLAYTON, Missouri 63105-2465

Agent Telephone:

Bond Number: 39S211924

Cross Reference:

Optime Care, Inc.
Attn: Cindy Hohn
Optime Care, Inc.
4060 Wedgeway Ct.
Earth City, Missouri 63045

We appreciate having you as a Liberty Mutual customer and we would like to thank you for allowing us to serve your bonding needs. This letter is to confirm Liberty Mutual Surety has received payment for your renewing bond.

The effective date of your renewing bond begins: September 7, 2020

Please review the enclosed documents for accuracy. You must remit the original of the Renew By Certificate and any supporting documents required to your obligee.

If you have any questions regarding this bond or would like to discuss your future bond needs, please contact your Liberty Mutual agent.

Again, thank you for entrusting us with your bonding needs.

Sincerely,
National Bond Center

For additional information regarding Liberty Mutual insurance products, please visit www.libertymutual.com

S-7089 7/04 IFD

St. Louis
12444 Powerscourt Drive
Saint Louis, Missouri 63131
+1 (888) 8480860 Fax: +1 (866) 5484962

CONTINUATION CERTIFICATE

To be attached to and form a part of surety bond number 39S211924 (the "Bond"), cross reference bond number _____, for Pharmaceutical Wholesaler Surety Bond

dated the 7th day of September, 2016, in the penal sum of $ 100,000.00 issued by The Ohio Casualty Insurance Company as surety (the "Surety"), on behalf of Optime Care, Inc. as principal (the "Principal"), in favor of State of Nevada, as obligee (the "Obligee").

The Surety hereby certifies that this Bond is continued in full force and effect until the 7th day of September, 2021, subject to all covenants and conditions of said Bond.

Said Bond has been continued in force upon the express condition that the full extent of the Surety's liability under said Bond, and this and all continuations thereof, for any loss or series of losses occurring during the entire time the Surety remains on said Bond, shall in no event, either individually or in the aggregate, exceed the penal sum of the Bond.

IN WITNESS WHEREOF, the Surety has set its hand and seal this 16th day of July, 2020

The Ohio Casualty Insurance Company
(Surety)

By: Timothy A. Mikolajewski

Timothy A. Mikolajewski
Assistant Secretary - Liberty Mutual Surety

THE OHIO CASUALTY INSURANCE COMPANY INCORPORATED 1919 NEW HAMPSHIRE

LMIC - 3300

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Optime Care Inc.

Pharmacy/Wholesaler License # (if applicable): WH02270

Physical Address: 4064 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address): 4060 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Telephone: 314-731-6900 Website: www.optimecare.com

Licensing Company Email: licensing@optimecare.com

Section 2: Personal Information

First: Amy Middle: Last: Kern

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: Sex ☐ M ■ F ☐ X

Mailing Address: 4060 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Telephone: 314-731-6900 Email: amy.kern@optimecare.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St Charles Community College		08/2005 - 05/2026	
Address	**City**	**State**	**Zip**
4601 Mid Rivers Mall Dr	Cottleville	MO	63376
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Ft Zumwalt North High School		08/01 - 05/05	
Address	**City**	**State**	**Zip**
1230 Tom Ginnever Ave	O Fallon	MO	63366
Diploma/Degree obtained, if any			
diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16 - current	[redacted]	[redacted]	MO	[redacted]
10/10 - 11/16			MO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Optime Care Inc.			07/18 - current	
Business Address		**City**	**State**	**Zip**
4064 Wedgeway Ct.		Earth City	MO	63045
Phone	**Title**		**Number of Employed Hours**	
314-731-6900	Designated Rep / Pharmacy Fulfillment Mgr		~15,000 hours	
Description of Duties				
Supervise, actively be involved with & aware of all distributor activities including receipt of product, drug shipments, inventory, returns, drug disposal/disposition, recordkeeping & training. Monitor state wholesale/distribution laws regularly.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/19/2025
Date

I, Amy Kern, **certify that as the designated representative for**

Optime Care Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AEK I am at least 21 years of age;
3. AEK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AEK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AEK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AEK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AEK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Amy Kern

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Kern

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of St. Charles

I, Amy E. Kern, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2025

Date

Subscribed and Sworn to before me this 19 day of November 2025

Rachel Christine Meyer

Notary Public Signature

RACHEL C MEYER
My Commission Expires
09-26-2026
NOTARY SEAL
St. Charles
County
Commission # 22877150
NOTARY PUBLIC - STATE OF MISSOURI
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Optime Care Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH02270

Physical Address: 4064 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 314-731-6900 Website: https://www.optimecare.com/

Licensing Company Email: licensing@optimecare.com

Section 2: Personal Information

First: Dea Middle: Taher Last: Belazi

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: PA Zip: [redacted]

Telephone: [redacted] Email: licensing@optimecare.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
John Hopkins University		7/2002 - 5/2004	
Address	**City**	**State**	**Zip**
3400 N. Charles Street	Baltimore	MD	21218
Diploma/Degree obtained, if any			
Masters Public Health			

School Name		From - To (MM/YY – MM/YY)	
University of Rhode Island		9/1995 - 5/2001	
Address	**City**	**State**	**Zip**
45 Upper College Road	Kingston	RI	02881
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
South Kingstown High School		9/1990 - 5/1995	
Address	**City**	**State**	**Zip**
215 Columbia Street	Wakefield	RI	02879
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2024 to present	[redacted]	[redacted]	PA	[redacted]
8/2017 - 5/2024			PA	
8/2010 - 8/2017			PA	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Optime Care Inc			12/2021 to present	
Business Address		**City**	**State**	**Zip**
1055 Westlakes Drive Suite 200		Berwyn	PA	19312
Phone	**Title**			
877-389-9040	Director			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
AscellaHealth			9/2013 to present	
Business Address		**City**	**State**	**Zip**
1055 Westlakes Drive Suite 200		Berwyn	PA	19312
Phone	**Title**			
877-389-9040	Chief Executive Officer			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # __4____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

While I have been named in certain lawsuits, either as an individual, member, partner, owner, officer or director of a company, no lawsuit has been related to any licensing matters or any proceeding before a licensing board or board of pharmacy.

Original Signature (electronic, copies or stamps not accepted)

10-2-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dea Belazi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-2-25

Date

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Chester

I, Dea Belazi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-2-25

Date

Subscribed and Sworn to before me this 2 day of October, 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JENNIFER KEYSER - Notary Public
Chester County
My Commission Expires May 30, 2029
Commission Number 1241109

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Optime Care Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH02270

Physical Address: 4064 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 314-731-6900 Website: https://www.optimecare.com/

Licensing Company Email: licensing@optimecare.com

Section 2: Personal Information

First: Billy Middle: Wayne Last: Oldham

Alias(es, nicknames, name changes, etc.): Bill

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: PA Zip: [redacted]

Telephone: [redacted] Email: licensing@optimecare.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Manchester Business School		1992 -1994	
Address	**City**	**State**	**Zip**
Booth St W	Manchester M15 6PB	UK	
Diploma/Degree obtained, if any			
Master of Business Administration, Entrepreneurship/Entrepreneurial Studies			

School Name		From - To (MM/YY – MM/YY)	
Harding University		graduated 1992	
Address	**City**	**State**	**Zip**
915 E. Market Street	Searcy	AK	72149
Diploma/Degree obtained, if any			
Bachelor of Business Administration, Economics			

School Name		From - To (MM/YY – MM/YY)	
Harding Academy		graduated 1988	
Address	**City**	**State**	**Zip**
1529 E. Park Ave.	Searcy	AK	72143
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]	[redacted]	VA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Optime Care Inc			12/2021 - Present
Business Address	**City**	**State**	**Zip**
1055 Westlakes Drive Suite 200	Berwyn	PA	19312
Phone	**Title**		
877-389-9040	President		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
AscellaHealth			9/2013 -Present
Business Address	**City**	**State**	**Zip**
1055 Westlakes Drive Suite 200	Berwyn	PA	19312
Phone	**Title**		
877-389-9040	Chairman & President		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Thought Leadership & Innovation Foundation			6/2021 - Present
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	Co-Founder & Chairman		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone			
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # __4___. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

While I have been named in certain lawsuits, either as an individual, member, partner, owner, officer or director of a company, no lawsuit has been related to any licensing matters or any proceeding before a licensing board or board of pharmacy.

Original Signature (electronic, copies or stamps not accepted)

10-2-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bill Oldham

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-2-25

Date

Please have this section completed in the presence of a Notary Public.

State of PA, ss. County of Chester

I, Bill Oldham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-2-25

Date

Subscribed and Sworn to before me this 2nd day of October, 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
JENNIFER KEYSER - Notary Public
Chester County
My Commission Expires May 30, 2029
Commission Number 1241109

(Seal)

OPTIME CARE INC EMPLOYEE ROSTER

EMPLOYEE	TYPE OF LICENSE	STATE	LICENSE/ REGISTRATION #
Sergio Barranco-Medina	PHARMACIST	MISSOURI	2016019830
Adam McIntosh	PHARMACIST	MISSOURI	2007027527
Alan Pham	PHARMACIST	MISSOURI	2020034349
Amanda Vazquez	PHARMACIST	MISSOURI	2015025614
Ashley Buehler	PHARMACIST	MISSOURI	2015027197
Brandon Salke	PHARMACIST	MISSOURI	2012027495
Elizabeth Maxfield	PHARMACIST	MISSOURI	2016027735
Erika Buettmann	PHARMACIST	MISSOURI	2015029009
Hannah Morgan	PHARMACIST	MISSOURI	2013030036
Jeffrey Allen	PHARMACIST	MISSOURI	2009027303
Julie Bowyer	PHARMACIST	MISSOURI	2009020975
Julie Price	PHARMACIST	MISSOURI	2012028246
Kacy Jetton	PHARMACIST	MISSOURI	2012026452
Kristen Melchior	PHARMACIST	MISSOURI	2002029697
Luann Quach	PHARMACIST	MISSOURI	2010000974
Matthew R Burns	PHARMACIST	MISSOURI	2007024424
Melissa Soriano	PHARMACIST	MISSOURI	2015025622
Molly Vanronzelen	PHARMACIST	MISSOURI	2011026564
Sarah Biehl	PHARMACIST	MISSOURI	2011008046
Sarah Halbmaier	PHARMACIST	MISSOURI	2014025396
Sean Levins	PHARMACIST	MISSOURI	2010026504
Soleil Youngclaus	PHARMACIST	MISSOURI	2010027754
Veronica Parks Smith	PHARMACIST	MISSOURI	2015028996
Amia Ringo	TECHNICIAN	MISSOURI	2025002499
Amber Bote	TECHNICIAN	MISSOURI	2014024246
Amy (Jimenez) Stallings	TECHNICIAN	MISSOURI	2015042416
Amy Kern	DESIGNATED REP TECHNICIAN	MISSOURI	2011011778
Amy Michelle Harris	TECHNICIAN	MISSOURI	2023048562
Amy Stein	TECHNICIAN	MISSOURI	2021046067
Angela Embree	TECHNICIAN	MISSOURI	2015041934
Angela Lewis	TECHNICIAN	MISSOURI	2014028877
Ann Marie Wyrsch	TECHNICIAN	MISSOURI	2018026986
Ashley Bush	TECHNICIAN	MISSOURI	2019030546
Auctayvia Snow	TECHNICIAN	MISSOURI	2025017020
Ayanna Barney	TECHNICIAN	MISSOURI	2023013749
Brianna Puni	TECHNICIAN	MISSOURI	2024042465
Brianna Resendiz	TECHNICIAN	MISSOURI	2025015626
Brittney L Alton	TECHNICIAN	MISSOURI	2023008202
Brittney Rice	TECHNICIAN	MISSOURI	2024031496
Christian Rodriguez	TECHNICIAN	MISSOURI	2022003608
Christine M Goldstein	TECHNICIAN	MISSOURI	2017032417
Christopher Prewitt-Allen	TECHNICIAN	MISSOURI	2010042817

EMPLOYEE	TYPE OF LICENSE	STATE	LICENSE/ REGISTRATION #
Clarissa Simmons	TECHNICIAN	MISSOURI	2024032080
Damita Mays	TECHNICIAN	MISSOURI	2023050613
Danielle Mendenhall	TECHNICIAN	MISSOURI	2015009664
Dapheney McKinney	TECHNICIAN	MISSOURI	2025005582
Darnishia Mims	TECHNICIAN	MISSOURI	2024038439
David Jeffrey Dee	TECHNICIAN	MISSOURI	2010030605
Davidra J Belk	TECHNICIAN	MISSOURI	2020037514
Dawn Goewert	TECHNICIAN	MISSOURI	2014003870
Debbie K Kolkmeier	TECHNICIAN	MISSOURI	2015040753
Destiny Allen	TECHNICIAN	MISSOURI	2023022417
Diane M Mottet	TECHNICIAN	MISSOURI	2000150825
Dianne Horner	TECHNICIAN	MISSOURI	200166331
Donna Roberts	TECHNICIAN	MISSOURI	2022040321
Ebone Clark	TECHNICIAN	MISSOURI	2015011098
Ebony Watkins-Keely	TECHNICIAN	MISSOURI	2023007364
Evan M Harris	TECHNICIAN	MISSOURI	2007013919
Gabe Janger	TECHNICIAN	MISSOURI	2025007253
Grace Right	TECHNICIAN	MISSOURI	2021006774
Holly F Sterling	TECHNICIAN	MISSOURI	2017043605
India E Pearson	TECHNICIAN	MISSOURI	2024047784
Jalissa Jackson	TECHNICIAN	MISSOURI	2025015043
Janay Harper	TECHNICIAN	MISSOURI	2021018840
Jasmine Jackson	TECHNICIAN	MISSOURI	2025015633
Jayda Allen	TECHNICIAN	MISSOURI	2022047149
Jeffrey Pelekanos	TECHNICIAN	MISSOURI	2018017642
Jessica Borak	TECHNICIAN	MISSOURI	2024025416
Jessica Clark	TECHNICIAN	MISSOURI	2023035101
Joseph M Paparic	TECHNICIAN	MISSOURI	2021020699
Kara Goodman	TECHNICIAN	MISSOURI	2015004035
Kara Sherrow	TECHNICIAN	MISSOURI	2019043391
Kary Jenkins	TECHNICIAN	MISSOURI	2021024207
Katie Money	TECHNICIAN	MISSOURI	2012015053
Katrina M Allen	TECHNICIAN	MISSOURI	2024028227
Kayla Sims	TECHNICIAN	MISSOURI	2024038173
Keira Riggins	TECHNICIAN	MISSOURI	2015034551
Kenyada Cole	TECHNICIAN	MISSOURI	2022043164
Kimberly Pickett	TECHNICIAN	MISSOURI	2008013626
Kyle Hayes	TECHNICIAN	MISSOURI	2015034994
Laeana Roth	TECHNICIAN	MISSOURI	2022001281
Latoya Foster Vinson	TECHNICIAN	MISSOURI	2010033844
Lori Michelle Ford	TECHNICIAN	MISSOURI	2025003433
Louis LaZear	TECHNICIAN	MISSOURI	2009008513
Lydia Bradley	TECHNICIAN	MISSOURI	2017009225
Makenzie Clay	TECHNICIAN	MISSOURI	2021039788
Margaretta Bell Breen	TECHNICIAN	MISSOURI	2016006234

EMPLOYEE	TYPE OF LICENSE	STATE	LICENSE/ REGISTRATION #
Marian D Aaron	TECHNICIAN	MISSOURI	2025011084
Marisa Fritschle	TECHNICIAN	MISSOURI	2022009419
Mary Harbin	TECHNICIAN	MISSOURI	2005030023
Marquetta Allen	TECHNICIAN	MISSOURI	2012003084
Mason Baker	TECHNICIAN	MISSOURI	2024061623
Mellanee Sherrow	TECHNICIAN	MISSOURI	2024028237
Meredith Buchanan	TECHNICIAN	MISSOURI	2017040837
Michelle Preston	TECHNICIAN	MISSOURI	2024001053
Nefrura Wilson	TECHNICIAN	MISSOURI	2020032947
Neri Henderson	TECHNICIAN	MISSOURI	2020015249
Nevaeh Smith	TECHNICIAN	MISSOURI	2020038360
Nicole Williams	TECHNICIAN	MISSOURI	2023045546
Peter Flores	TECHNICIAN	MISSOURI	2008022782
Rachel Richardson	TECHNICIAN	MISSOURI	2010037770
Randip Krishan Sroya	TECHNICIAN	MISSOURI	2025015738
Ranicia Person	TECHNICIAN	MISSOURI	2024039182
Rayiana Thompson	TECHNICIAN	MISSOURI	2024045626
Raymond Fischer	TECHNICIAN	MISSOURI	2015011101
Regina Wilson	TECHNICIAN	MISSOURI	2024039765
Remeika McCoy	TECHNICIAN	MISSOURI	2025017564
Richard Spillers	TECHNICIAN	MISSOURI	2025012876
Rita Orozco	TECHNICIAN	MISSOURI	2024041808
Rochelle Buckner	TECHNICIAN	MISSOURI	2015024448
Samantha Roberts	TECHNICIAN	MISSOURI	2024034041
Sara Coussens	TECHNICIAN	MISSOURI	2023048564
Selena Sadler	TECHNICIAN	MISSOURI	2018008267
Shah Sharif	TECHNICIAN	MISSOURI	2025015778
Shannon Murply	TECHNICIAN	MISSOURI	2021047342
Shakira Barry	TECHNICIAN	MISSOURI	2024025422
Shalonda Walters	TECHNICIAN	MISSOURI	2024045825
Sharaz Harrison	TECHNICIAN	MISSOURI	2022006077
Shontay Sweat	TECHNICIAN	MISSOURI	2025005373
Sierra Shaeffer	TECHNICIAN	MISSOURI	2025004065
Synia Gathing	TECHNICIAN	MISSOURI	2020012936
Tawyna Parker	TECHNICIAN	MISSOURI	2023043206
Terrence Leachman	TECHNICIAN	MISSOURI	2023006634
Theanessa Sue Yancie	TECHNICIAN	MISSOURI	2000147787
Tiara Nicole Stewart	TECHNICIAN	MISSOURI	2024002595
Tiffanie Rives	TECHNICIAN	MISSOURI	2024006688
Tiffany Smith	TECHNICIAN	MISSOURI	2019011700
Tiska Swink	TECHNICIAN	MISSOURI	2005031424
Tracey B Miller	TECHNICIAN	MISSOURI	2014019067
William A Bertetto	TECHNICIAN	MISSOURI	2025012192
Winta Kula	TECHNICIAN	MISSOURI	2024016776

4Q

WH03734

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH03734	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Teleflex LLC

Physical Address: 16 Elizabeth Drive

City: Chelmsford State: MA Zip: 01824

Mailing Address (if different from physical address): Teleflex LLC attention Bettina Knight 3015 Carrington Mill Blvd

City: Morrisville State: NC Zip: 27560

Telephone: _____ Website: https://teleflex.com

Name of Designated Representative (DR): Bernarda Cedeno Morel

Licensing Company Email: statelicensing@teleflex.com DR Email: bernarda.morel@teleflex.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: wholesaler, distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Teleflex Logistics LLC

Corporation/Organization Name: Teleflex LLC

Mailing Address: Teleflex LLC attention Bettina Knight 3015 Carrington Mill Blvd

City: Morrisville State: NC Zip: 27560

Telephone: 919-544-8000 Email: statelicensing@teleflex.com

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Teleflex LLC

Facility Name

Jacob Newman

Print Name of Authorized Person Submitting Application

Jacob Newman

Original signature of Authorized Person (copies or stamps not accepted)

10/6/25

Date

Board Use Only	Date Received: 10/8/25	Amount: $1000 cc

NABP ACCREDITED
DRUG DISTRIBUTOR

Teleflex LLC

located at

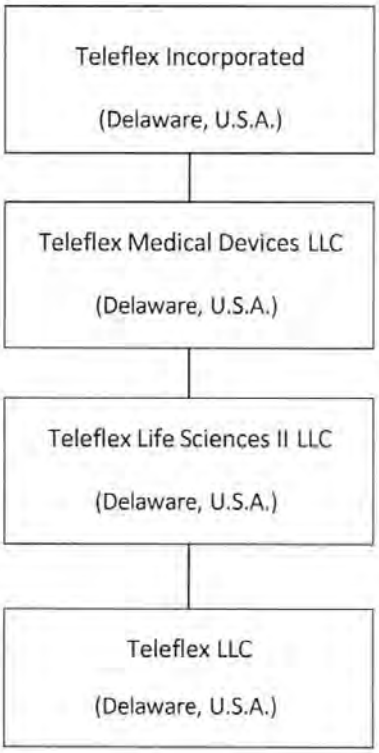
16 Elizabeth Dr, Chelmsford, MA 01824

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

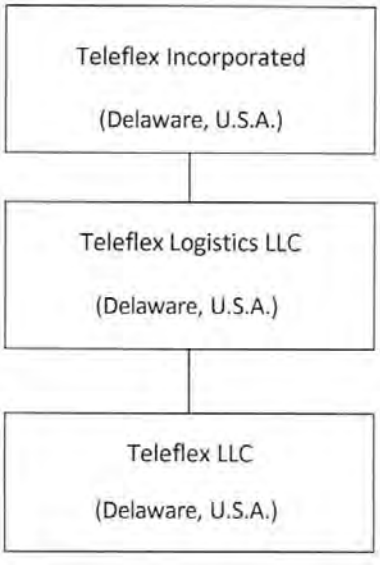
Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

0650

Teleflex LLC
2024



Teleflex LLC
2025



FIFTH AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

OF

TELEFLEX LLC

This Fifth Amended and Restated Limited Liability Company Agreement of Teleflex LLC is effective as of May 20, 2025 (the "***Effective Date***").

RECITALS

A. Teleflex LLC, a Delaware limited liability company (the "***Company***"), was formed by Teleflex Incorporated (the "***Initial Member***") on August 20, 2018 (the "***Formation Date***") by the filing of the certificate of formation of the Company (as amended from time to time, the "***Certificate***") with the Office of the Secretary of State of the State of Delaware.

B. Prior to the Effective Date, the Initial Member was the sole member of the Company and the Company was governed pursuant to the terms and provisions of that certain Limited Liability Company Agreement of Teleflex LLC dated August 20, 2018.

C. On February 21, 2020, Teleflex Life Sciences Limited, a company formed and existing under the laws of Malta, having its registered office at 171, Old Bakery Street, Valletta, VLT 1455, Malta, and registered with the Malta Business Registry under registration number C94305 ("***TLS***"), acquired the Initial Member's Interest in the Company and became a member of the Company (the "***TLS Acquisition***").

D. Following the Acquisition, the Company issued an additional Interest in the Company to Teleflex General Partner LLC, a Delaware limited liability company ("***TGP***"), the Company was governed pursuant to the terms and provisions of that certain Amended and Restated Limited Liability Company Agreement of Teleflex LLC dated February 21, 2020, and TLS and TGP were the members of the Company.

E. On December 15, 2023, TLS assigned and transferred its 99.999% Interest in the Company to Teleflex Medical Devices LLC, a Delaware limited liability company ("***TMD***"), and TMD was admitted as a member of the Company, together with TGP, and the Company was governed pursuant to the terms and provisions of that certain Second Amended and Restated Limited Liability Company Agreement of Teleflex LLC dated December 15, 2023.

F. On December 16, 2023, TMD assigned and transferred its 99.999% Interest in the Company to Teleflex Technologies LLC, a Delaware limited liability company ("***TTech***" or and TTech was admitted as a member of the Company, together with TGP, and the Company was governed pursuant to the terms and provisions of that certain Third Amended and Restated Limited Liability Company Agreement of Teleflex LLC dated December 16, 2023.

G. On December 18, 2023, TGP merged with into TTech and as a result of the merger, TTech became the sole member of the Company.

H. On December 19, 2023, TTech filed a certificate of amendment with the Delaware Secretary of State and changed its name to Teleflex Life Sciences II LLC ("***TLS II***"), and the Company was governed pursuant to the terms and provisions of that certain Fourth Amended and Restated Limited

Liability Company Agreement of Teleflex LLC dated December 19, 2023 (the "***Prior Agreement***") with TLS II as its sole member following the name change and merger.

I. On May 20, 2025 TLS II assigned and transferred its entire Interest in the Company to Teleflex Logistics LLC, a Delaware limited liability company ("***Teleflex Logistics***" or the "***Member***").

Teleflex Logistics, as the sole Member of the Company following the assignment, desires to amend and restate the Prior Agreement in its entirety to provide for the terms and provisions relating to its ongoing ownership and management of the Company.

Accordingly, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS

Capitalized terms used but not otherwise defined in this agreement have the meanings given to those terms in Exhibit A.

ARTICLE II
GENERAL PROVISIONS

2.1 Formation of Limited Liability Company

The Company was formed as a Delaware limited liability company on the Formation Date by the filing of the Certificate with the Office of the Secretary of State of the State of Delaware under and pursuant to the Act. The Board will file or cause to be filed all such other certificates, notices, statements, amendments or other instruments required by law for the continued operation of the Company as a limited liability company.

2.2 Name of Company

The name of the Company is "Teleflex LLC." The business of the Company may be conducted under any name chosen by the Member, and the Member may, in its sole discretion consistent with the requirements of the Act, change the name of the Company from time to time.

2.3 Principal Place of Business; Registered Agent for Process

(a) The principal office of the Company will be at such place as the Member may designate, in its sole discretion, from time to time.

(b) The registered office of the Company in the State of Delaware will be at such place as the Member may designate, in its sole discretion, from time to time. The registered agent of the Company in the State of Delaware to accept service of process will be such Person as the Member may designate, in its sole discretion, from time to time.

2.4 Term of Company

The term of the Company commenced on the date the Certificate was filed in the office of the Secretary of State of the State of Delaware in accordance with the Act and will continue until terminated pursuant to Section 9.1.

2.5 Purposes

The Company is organized for the purpose of carrying on any lawful business, as determined appropriate by the Board. Notwithstanding the preceding sentence, the Company may execute and deliver and perform all contracts and other undertakings and engage in all the activities and transactions that may, in the opinion of the Board, be necessary or advisable to carry out the foregoing purposes, subject to the limitations contained in this agreement and the Act. The Board shall cause the Company to be qualified or registered under applicable laws of any jurisdiction in which the Company transacts business and shall be authorized to execute, deliver and file any certificates and documents necessary to effect such qualification or registration, including without limitation the appointment of agents for service of process in such jurisdictions.

2.6 Title to Company Property

All property owned by the Company is to be deemed to be owned by the Company as an entity, and the Member will not have any direct ownership interest in any such property.

2.7 Failure to Observe Formalities

A failure to observe any formalities or requirements of this agreement, the Certificate or the Act will not be grounds for imposing personal liability on the Member or the Managers for liabilities of the Company.

2.8 No Partnership Intended for Nontax Purposes

The Member has formed the Company under the Act, and expressly denies any intent hereby to form a partnership or a corporation under applicable law.

2.9 Liability of the Member to Third Parties; No Reliance by Third-Party Creditors

(a) Except as otherwise provided in the Act, the Member will not be personally liable for any debt, obligation or liability of the Company, whether arising in contract or otherwise, by reason of being a member of the Company.

(b) This agreement is entered into by the Member for the exclusive benefit of the Member and their successors and assigns. This agreement is expressly not intended for the benefit of any creditor of the Company or any other Person. Except and only to the extent provided by applicable statute, no such creditor or third party has any rights under this agreement or any agreement between the Company and the Member with respect to any contributions or otherwise.

2.10 Fiscal Year

The fiscal year of the Company shall begin on January 1st and end on December 31st, provided that the initial fiscal year of the Company shall begin as of the Formation Date.

2.11 Functional Currency

The functional currency of the Company shall be United States Dollars.

ARTICLE III
MEMBER

3.1 Member

The Company is owned exclusively by the Member pursuant to the terms of this agreement. In the event the Company has more than one Member, this agreement will have no further force and effect. No Interest in the Company shall be represented by a separate certificate.

3.2 Capital

The Member may (but is not required to) contribute capital to the Company in such amounts and at such times as it may determine in its discretion.

ARTICLE IV
ALLOCATION OF NET INCOME AND NET LOSS

All items of Net Income or Net Loss will be allocated exclusively to the Member.

ARTICLE V
DISTRIBUTIONS

Net Cash Flow and Company assets in kind will be distributed in such amounts, and at such times as the Board may in its absolute discretion determine. Any such distribution will be made exclusively to the Member.

ARTICLE VI
MANAGEMENT

6.1 Management Vested in the Board of Managers

As provided and subject to the terms herein, a board of Managers (the "***Board***") has the authority to manage the business and affairs of the Company. Any action required to be taken by the Board will be duly taken if approved, in writing or otherwise, by the Board as required by the terms of this agreement.

6.2 Composition of Board

6.1.1 Number of Managers

The Board will be composed of three (3) Managers, who are specified in Section 6.2.2. The number of Managers may be changed by the Member from time to time.

6.2.2 Appointment of Managers

As of the Effective Date, the Managers are John Deren, Mikhail Kryukov and Matthew Howald.

6.2.2 Term of Managers

Each Manager will hold office until such Manager dies, resigns or is otherwise removed pursuant to Section 6.2.2. Any Manager may resign at any time by delivering written notice to the Member. Any such resignation will be effective upon delivery thereof unless the notice of resignation specifies a later effective date. The acceptance of such resignation by the Member will not be necessary to make it effective.

6.2.3 Removal of Manager

A Manager may be removed with or without cause at any time by the unanimous written consent of the Member.

6.2.4 Filling a Vacancy

Any vacancy occurring on the Board is to be filled by an appointee as designated by the Member. The term of any replacement Manager will extend to the remainder of the term of the departed Manager.

6.3 Manner of Acting

The act of a majority of the number of Managers (whether by vote at a meeting of the Board or by written consent) will be the act of the Board, unless the vote of a greater number is required by this agreement, the Certificate or the Act.

6.4 Compensation

Unless approved by the Member, the Managers will not be paid any compensation in connection with their service as a Manager. Notwithstanding the preceding sentence, no Manager is precluded from serving the Company in any other capacity and receiving compensation therefor.

6.5 Authority of the Board

6.4.1 Authority of the Board

Except as otherwise provided herein, the Board is vested with complete management and control of the affairs of the Company, except to the extent that the Board delegates authority to one or more Officers or other Persons designated by the Board. Except as otherwise provided herein, the Manager has the power and authority to do all things necessary or proper to carry out the purposes of the Company. All actions taken by the Board will be subject to the terms of this agreement. In their capacity as Managers, the Managers are specifically authorized to execute authorized instruments, documents, agreements, contracts and other undertakings on behalf and in the name of the Company, and parties dealing with the Company are entitled to rely on the authority of each Manager to execute such documents on behalf of the Company. In addition, the Board may delegate to one or more Persons the authority to execute authorized instruments, documents, agreements, contracts and other undertakings on behalf and in the name of the Company.

6.4.2 Limitation on Authority of the Board

The Board, without the unanimous written consent of the Member, has no authority to:

(a) cause the issuance or sale of any additional Interests in the Company;

(b) amend this agreement;

(c) effect a merger of the Company or the sale, lease, exchange or other disposition of all, or substantially all, the Company's property, or any other similar business combination pursuant to which any Interest of the Company is converted into or exchanged for cash, securities or other property of an acquiring entity or any of its affiliates; provided that the Board may effect such a transaction that only involves the Company and one or more other entities part of the Teleflex Incorporated commonly controlled group of companies without prior written consent of the Member;

(d) cause the Company to acquire any business by sale, lease, assignment or other transfer or conveyance of assets, property or securities or by merger or other form of business combination or otherwise, or make any agreement or become obligated to do so;

(e) do any act that would contravene this agreement;

(f) do any act that would make it impossible to carry on the ordinary business of the Company; or

(g) possess Company property, or assign rights in Company property, for other than a Company purpose.

6.6 Obligations of Managers

Each Manager is to devote such business time to the Company as may be reasonably necessary to manage the affairs and activities of the Company.

6.7 Payment and Reimbursement of Expenses

The Company will reimburse the Managers and the Member for all reasonable expenses incurred by them on behalf of the Company, including without limitation attorneys' fees, filing fees, and other expenses and charges incurred, and that may be incurred, in connection with the formation of the Company.

ARTICLE VII
OFFICERS

7.1 Authority to Delegate to Officers

The Board has the power and authority to appoint Officers of the Company. Officers have such authority, perform such duties and hold office for such period as may be prescribed by the Board. The Board may delegate to any Officer the power to appoint any subordinate Officers and to prescribe their respective terms of office, authority and duties. Any two or more offices may be held by the same Person.

Unless an Officer dies, resigns or is removed from office, he or she will hold office until his or her successor is appointed.

7.2 Resignation or Removal

Any Officer of the Company may resign from such position by delivering written notice of the resignation to the Board. Any Officer may be removed by the Board, with or without cause, upon receiving written notice from the Board. Election or appointment of an Officer will not of itself create any contractual right to continued employment, compensation or other benefit from the Company. Vacancies in any office caused by any reason may be filled by the Board by selecting an individual to act during the unexpired term.

7.3 Salaries

The compensation of any Officers, agents or other employees of the Company is to be fixed by the Board, and may be changed from time to time by the Board.

7.4 Signing Authority

The Board may authorize any Officer or Officers, or agent or agents, to enter into any contract or execute and deliver any instrument in the name of and on behalf of the Company. Such authority may be general or confined to specific instances. All checks, drafts or other orders for the payment of money, notes or other evidences of indebtedness issued in the name of the Company may be signed by such Officer or Officers, or agent or agents, of the Company as is from time to time determined by the Board and in such manner as is from time to time determined by the Board.

7.5 Appointment of Officers

As of the Effective Date, the Officers of the Company are as follows:

- Mikhail Kryukov, Vice President & Secretary
- Matthew Howald, Vice President & Treasurer; and
- John R. Deren, President.

ARTICLE VIII
INDEMNIFICATION

8.1 Limitation on Liability

No Member, Manager or Officer, or employee, shareholder, member, partner, delegate or agent thereof, will be liable, responsible or accountable in damages or otherwise to the Company or the Member for any act or omission by any such Person if such Person acted in good faith and in a manner in which he, she or it believed to be in the best interests of the Company unless such conduct constitutes fraud, gross negligence, willful misconduct or a material breach of this agreement.

8.2 Indemnification

To the fullest extent not prohibited by law, the Company will indemnify and hold harmless the Member, each Manager and each Officer, and each employee, shareholder, member, partner, delegate or agent thereof, from and against any and all losses, claims, demands, costs, damages, liabilities (joint and several), expenses of any nature (including without limitation attorneys' fees and disbursements), judgments, fines, settlements and other amounts arising from any and all claims, demands, actions, suits or proceedings, civil, criminal, administrative or investigative, in which such Person may be involved or threatened to be involved, as a party or otherwise, arising out of or incidental to any business of the Company transacted or occurring while such Person was a member, Manager or Officer, or employee, shareholder, member, partner, delegate or agent thereof, regardless of whether such Person continues in such capacity at the time any such liability or expense is paid or incurred, except for fraud, gross negligence, willful misconduct or bad faith on the part of such Person. The indemnification provided by this Section 8.2 will be in addition to any other rights to which those indemnified may be entitled under any agreement, as a matter of law or equity, or otherwise, and will continue as to a Person who has ceased to serve in their capacity, and will inure to the benefit of the heirs, successors, assigns and administrators of the Person so indemnified. With respect to the satisfaction of any indemnification of the above-mentioned Persons, only assets of the Company will be available therefor and the Member will not have any personal liability therefor. Any indemnification required hereunder to be made by the Company will be made promptly after the liability, loss, damage, cost or expense is incurred or suffered. The Board may establish reasonable procedures for the submission of claims for indemnification pursuant to this Section 8.2, determination of the entitlement of any Person thereto and review of any such determination.

8.3 Advancement of Expenses

The right to indemnification conferred in this Article VIII includes the right to be paid by the Company the expenses incurred in defending any proceeding in advance of its final disposition. An advancement of expenses must be made upon delivery to the Company of an undertaking, by or on behalf of such indemnitee, to repay all amounts so advanced if it is ultimately determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses under this Section 8.3.

ARTICLE IX
DISSOLUTION AND TERMINATION

9.1 Events of Dissolution

(a) The Company may be dissolved on a date designated by the Member.

(b) Subject to the foregoing, the death, retirement, resignation, expulsion, bankruptcy or dissolution of a Member or the occurrence of any other event that terminates the continued membership of a Member will not cause the Company to be dissolved or its affairs to be wound up, and upon the occurrence of any such event, the limited liability company will be continued without dissolution.

9.2 Effectiveness of Dissolution

Dissolution of the Company will be effective on the date on which the event occurs giving rise to the dissolution, but the Company may not terminate until the assets of the Company have been

distributed as provided herein. Notwithstanding the dissolution of the Company, prior to the termination of the Company, as aforesaid, the business of the Company and the affairs of the Member, as such, will continue to be governed by this agreement. Upon dissolution, the Member must cause the assets of the Company to be liquidated and must cause the proceeds thereof to be applied and distributed as contemplated by this agreement.

9.3 Distributions Upon Liquidation

Distributions upon liquidation of the Company, after payment to all creditors, are to be made to the Member.

ARTICLE X
BOOKS, RECORDS AND BANK ACCOUNTS

10.1 Books and Records

(a) The books and records of the Company will be maintained at the principal office of the Company.

(b) The Company will maintain with its books and records the following: (1) a current list of the full name and last known address of the Member; (2) a copy of the Certificate, and all certificates of amendment thereto; (3) copies of the Company's federal, state and local tax returns and reports, if any, for the three most recent fiscal years; (4) copies of this agreement and any amendments thereto; and (5) copies of all financial statements for the Company for the three most recent fiscal years.

10.2 Bank Accounts

The Board is responsible for causing one or more accounts to be maintained in a bank (or banks), as necessary, which accounts are to be used for the payment of expenditures incurred in connection with the business of the Company, and in which are to be deposited any and all cash receipts. All such amounts are to be received, held and disbursed by the Company for the purposes specified in this agreement. There may not be deposited in any of such accounts any funds other than funds belonging to the Company, and no other funds will in any way be commingled with such funds.

ARTICLE XI
MISCELLANEOUS

11.1 Successors and Assigns

This agreement, and each and every provision hereof, will be binding on and will inure to the benefit of the Member, their respective successors, heirs, successors in title and assigns, and each and every successor in interest to any Member, whether such successor acquires an Interest by way of gift, purchase, foreclosure or by any other method, will hold such Interest subject to all the terms and provisions of this agreement.

11.2 Amendment of Agreement

Except as otherwise provided herein, this agreement may be amended only upon the unanimous written consent of the Member.

11.3 Captions

Titles or captions of articles or sections contained in this agreement are inserted only as a matter of convenience and for reference, and in no way define, limit, extend or describe the scope of this agreement or the intent of any provisions hereof.

11.4 Applicable Law

This agreement and the rights and obligations of the parties hereunder are to be governed by and interpreted, construed and enforced in accordance with the laws of the State of Delaware (regardless of the choice of law principles of the State of Delaware or of any other jurisdiction).

11.5 Severability

If any provision of this agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the provisions shall remain in full force and effect and shall in no way be affected, impaired or invalidated.

Docusign Envelope ID: 8D1058E8-20CC-4EC1-AF11-7FDD50B2F4C8

The Member has executed this Fifth Amended and Restated Limited Liability Company Agreement as of the Effective Date.

MEMBER:

TELEFLEX LOGISTICS LLC

DocuSigned by:
Matt Howald
74CDEFA2F47641C...

By: Matthew Howald
Its: Manager

EXHIBIT A

DEFINITIONS

Capitalized terms used in this agreement have the following meanings:

"***Act***" means the Delaware Limited Liability Company Act, as amended from time to time.

"***Interest***" means the entire ownership interest of a Member in the Company at any particular time, including without limitation the right of such Member to any and all benefits to which such Member may be entitled as provided in this agreement, together with the obligations of such Member to comply with all the terms and provisions of this agreement.

"***Member***" means Teleflex Logistics LLC and any other Person that may be admitted as a member of the Company subsequent to the Effective Date, in each case in their capacity as a member of the Company and for so long as they remain a member of the Company.

"***Net Cash Flow***" means, for each fiscal year or other period, the gross cash proceeds received by the Company for such year or period, less cash expenditures of the Company for such year or period, less reserves for future Company expenditures as determined by the Member.

"***Net Income***" and "***Net Loss***" mean, for each fiscal year or other period, an amount equal to the Company's realized and unrealized net income or net loss for such fiscal year or other period.

"***Officer***" means a Person designated or appointed as an officer of the Company pursuant to Article VII.

"***Person***" means any individual, corporation, partnership, trust, limited liability company or other entity.

Teleflex®

Teleflex

3015 Carrington Mill Blvd
Morrisville, NC 27560
USA
Phone: 919-361-4150
Fax: 919-361-3905

teleflex.com

January 13, 2026

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

Subject: Change of Officer for licenses # WH01856 Teleflex LLC in MS
WH03764 Teleflex LLC in MA

To Whom It May Concern,

Please find attached the updated document regarding the Officer of Teleflex LLC

Please feel free to contact me using the information below if you have questions or concerns.

Kind regards,

Bettina Knight

Bettina Knight
State Licensing Lead

Teleflex

OFFICERS OF TELEFLEX LLC

OFFICERS	*TITLE*
Jake Newman jake.newman@teleflex.com ***Manager**	***President***
Daniel Logue daniel.logue@teleflex.com ***Manager**	***Vice President & Secretary***
Marina Zivik Marina.zivik@teleflex.com ***Manager**	***Vice President***
Matthew Howald matt.howald@teleflex.com ***Manager**	***Vice President, & Treasurer***

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TELEFLEX LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF MAY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TELEFLEX LLC" WAS FORMED ON THE TWENTIETH DAY OF AUGUST, A.D. 2018.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7023120 8300

SR# 20252281803

Authentication: 203691441

Date: 05-14-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Home state - Massachusetts

Massachusetts only licenses facilities distributing controlled substances.

The facility does not handle prescription drugs recognized as controlled substances in Massachusetts, therefore no home license is needed.

Attached is an email from the MA Board of Pharmacy that confirms the facility located in Chelmsford, MA does not need a home state license.

For more information, see Massachusetts Controlled Substance Registration:

https://www.mass.gov/orgs/massachusetts-controlled-substances-registration.

From: Admin, Pharmacy (DPH)
To: Knight, Bettina
Subject: Re: IABP Pumps - license
Date: Monday, April 8, 2024 10:03:14 AM
Attachments: Outlook-rnrz34mo.png

Hello-
The Board does not license these facilities.

Please review the Drug Control Program's website to determine if a registration is required by that agency:
https://www.mass.gov/orgs/massachusetts-controlled-substances-registration

Thank you.

Massachusetts Board of Registration in Pharmacy
250 Washington Street
Boston, MA 02108
pharmacy.admin@mass.gov
(617) 973-0960

Renewal reminders are now only sent by email.
Please keep your **email address and other contact information updated** using this link:
https://healthprofessionlicensing.mass.gov/login-register

Consider being added to the Board's email distribution list so you are notified of changes to MA regulations and other updates by emailing us at pharmacy.admin@mass.gov

150 YEARS
OF ADVANCING
PUBLIC
HEALTH

When writing or responding, please remember that the Secretary of State's Office has determined that e-mail is a public record.

From: Knight, Bettina <Bettina.Knight@teleflex.com>
Sent: Monday, April 8, 2024 10:00 AM
To: Admin, Pharmacy (DPH) <Pharmacy.Admin@MassMail.State.MA.US>
Subject: IABP Pumps - license

CAUTION: This email originated from a sender outside of the Commonwealth of Massachusetts mail system. Do not click on links or open attachments unless you recognize the sender and know the content is safe.

Good morning,

I am responsible for maintaining state licenses for all the Teleflex facilities.

Our facility in Massachusetts manufactures Intra-Aortic Balloon (IAB) Pumps which are designed to assist patients who need mechanical circulatory support during cardiac events. The IAB Pump uses Helium to inflate and deflate the balloon. In connection with the distribution of the IAB Pumps, the facility will distribute Helium tanks, which are labeled as "Rx-Only".

Bases upon our reading of the Pharmacy law, the facility is not required to be licenses in MA. In connection with sales/shipments of the products into the other states, we need to obtain wholesaler/manufacturer licenses. Most applications require a copy of the home state license. Would it be possible to get a letter from the MA Board of Pharmacy to confirm that the facility does not need a home license?

Let me know if you need more information.

Kind regards

Bettina

Bettina Knight (she/her)
State Licensing Lead

[redacted]

Teleflex

This e-mail message, including any attachment(s), is for the sole use of the intended recipient(s) and may contain confidential, proprietary and/or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please notify the sender by reply e-mail and delete, and/or otherwise destroy, all copies of the original message, including any attachment(s).

Please consider the environment before printing this email

MEMORANDUM OF INSURANCE	DATE 28-Aug-2025

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of Marsh is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://marshdigital.marsh.com/marshconnect/viewMOI.action?clientId=582422257. The information contained herein is as of the date referred to above. Marsh shall be under no obligation to update such information.

PRODUCER	COMPANIES AFFORDING COVERAGE
Marsh USA LLC ("Marsh")	Co. A Travelers Property Casualty Company of America
INSURED Teleflex Incorporated and Subsidiaries 550 E. Swedesford Road Suite 400, Wayne Pennsylvania 19087 United States	Co. B Travelers Casualty & Surety Company
	Co. C Columbia Casualty Company
	Co. D
	Co. E
	Co. F

COVERAGES

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS MEMORANDUM MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS

CO LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE	POLICY EXPIRATION DATE	LIMITS (LIMITS IN USD UNLESS OTHERWISE INDICATED)	
A	GENERAL LIABILITY Commercial General Liability Occurrence	TJGLSA2J706154TIL25	01-Sep-2025	01-Sep-2026	GENERAL AGGREGATE	2,000,000
					PRODUCTS - COMP/OP AGG	Excluded
					PERSONAL AND ADV INJURY	1,000,000
					EACH OCCURRENCE	1,000,000
					FIRE DAMAGE (ANY ONE FIRE)	1,000,000
					MED EXP (ANY ONE PERSON)	5,000
A	AUTOMOBILE LIABILITY Any Auto Hired Autos Non-Owned Autos	TJCAP2J706166TIL25	01-Sep-2025	01-Sep-2026	COMBINED SINGLE LIMIT	2,000,000
					BODILY INJURY (PER PERSON)	
					BODILY INJURY (PER ACCIDENT)	
					PROPERTY DAMAGE	
A	EXCESS LIABILITY Other than Umbrella Form	EX6S79096125NF	01-Sep-2025	01-Sep-2026	EACH OCCURENCE	10,000,000
					AGGREGATE	10,000,000
A	WORKERS COMPENSATION / EMPLOYERS LIABILITY THE PROPRIETOR / PARTNERS / EXECUTIVE OFFICERS ARE Included	UB8N3139892551K (AOS)	01-Sep-2025	01-Sep-2026	WORKERS COMP LIMITS	Statutory
B		UB8N3113332551R (Retro)	01-Sep-2025	01-Sep-2026	EL EACH ACCIDENT	1,000,000
					EL DISEASE - POLICY LIMIT	1,000,000
					EL DISEASE - EACH EMPLOYEE	1,000,000

C	Primary Products Liability - Clinical Trials	ADT2091141649	01-Sep-2025	01-Sep-2026	Each Claim / Aggregate	15,000,000 / 15,000,000

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications here to are not authorized.

MEMORANDUM OF INSURANCE | **DATE** 28-Aug-2025

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PRODUCER
Marsh USA LLC
("Marsh")

INSURED
Teleflex Incorporated and Subsidiaries
550 E. Swedesford Road
Suite 400, Wayne
Pennsylvania 19087
United States

ADDITIONAL INFORMATION
ADDITIONAL INFORMATION
Provisions that we can include upon request:
Automobile
1. Broad Named Insured
2. Employees as Insureds
3. Additional Insured Lessor and Loss Payee as Required by Written Contract.

Workers Compensation:
1. Waiver of Subrogation as Required by Written Contract

General Liability and Premises Operations:
1. Broad Named Insured
2. Blanket Additional Insured as Required by Written Contract
3. Waiver of Subrogation as Required by Written Contract

Products Liability:
1. Worldwide Coverage Territory
2. Vendors are included as insureds as required by written contract
3. See key policy definition of Insured Product below
Note:
Excess Liability applies over General Liability, Automobile Liability and Employers Liability.

CNA policy definition of Insured Product
INSURED PRODUCT
Insured product means any goods or products:
A. manufactured, developed, designed, created, or tested;
B. sold, leased, licensed, rented, handled, marketed, distributed to others; or
C. disposed of;
by the Insured Entity or others on the Insured Entitys behalf, including but not limited to:
1. biological products, pharmaceutical drugs, medical devices, nutraceuticals; or
2. products that are used, or are intended for use in clinical trials, health care or the providing of

professional services; or
3. containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.
Insured product includes:
a. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of insured product; and
b. the providing of or failure to provide warnings or instructions.

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications hereto are not authorized.

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800142112

Application/License No. _____

Teleflex LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 16 Elizabeth Drive, Chelmsford, MA 01824 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800, Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 17, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17 day of July, 2024.

APPLICANT/PRINCIPAL

Teleflex LLC

Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

Surety Company's Representative

Bianca M. Phillips, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

NA

intact INSURANCE

Power of Attorney

Surety Bond No: 800142112

Principal: Teleflex LLC

Obligee: Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: Bianca M. Phillips, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 17th day of July, 2024

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Teleflex LLC MDEG License # (if applicable) ____

Physical Address 16 Elizabeth Drive

City Chelmsford State MA Zip 01824

Mailing Address (if different from physical address) 3015 Carrington Mill Blvd

City Morrisville State NC Zip 27560

Telephone 662-892-9100 Website https://www.teleflex.com

Licensing Company Email statelicensing@teleflex.com

Section 2: Personal Information

First Bernarda Middle ____ Last Morel

Alias(es, nicknames, name changes, etc.) ____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State MA Zip [redacted]

Telephone [redacted] Email bernarda.morel@teleflex.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Aristides Garcias Mella			
Address	City	State	Zip
La Romana Dominican Republic	La Romana	PR	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Academia de Belleza Nacidit		1980-1984	
Address	City	State	Zip
712 Santo Domingo este	Santo Domingo	PR	
Diploma/Degree obtained, if any			
highschool diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2014- present	[redacted]	[redacted]	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Teleflex LLC		11/14/2000 - present	
Business Address	**City**	**State**	**Zip**
16 Elizabeth Drive	Chelmsford	MA	01824
Phone	**Title**	**Number of Employed Hours**	
978-250-5100	Quality Control Manager	65,000	
Description of Duties			
Manage the incoming, in process and final release of products. Manage a team of around 20 employees. Coordinate the shipping of sterile products.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

17 Oct 2025
Date

Bernarda Morel, **certify that as the MDEG Administrator for**

Teleflex LLC,

that I (initial that you have read and meet the following requirements):

1. BCM Have a high school diploma or its equivalent;
2. BCM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BCM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BCM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BERNARDA C. MOREL

Print Name (First, Last)

BCMorel

Original Signature (electronic, copies or stamps not accepted)

17 Oct 2025

Date

Board Use Only	Date Received: 10/27/25

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Teleflex LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 16 Elizabeth Drive

City Chelmsford State MA Zip 01824

Mailing Address (if different from physical address) Teleflex LLC attention Bettina Knight 3015 Carrington Mill Blvd

City Morrisville State NC Zip 27560

Telephone 978-250-5100 Website https://www.teleflex.com

Licensing Company Email statelicensing@teleflex.com

Section 2: Personal Information

First Bernada Middle _____ Last Cedeno Morel

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted]

City [redacted] State MA Zip [redacted]

Telephone [redacted] Email bernarda.morel@teleflex.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Aristides Garcias Mella			
Address	**City**	**State**	**Zip**
La Romana Dominican Republic	La Romana		
Diploma/Degree obtained, if any			
High school degree			

School Name		From - To (MM/YY – MM/YY)	
Academia de Belleza Nacidit		1980-1984	
Address	**City**	**State**	**Zip**
712 Santo Domingo Este	Santo Domingo, DR		
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2014 - present	[redacted]	[redacted]	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Teleflex LLC			11/14/2000 - present	
Business Address		**City**	**State**	**Zip**
16 Elizabeth Drive		Chelmsford	MA	01824
Phone	**Title**		**Number of Employed Hours**	
978-250-5100	Quality Control Manager		65,000.00	
Description of Duties				
Manage the incoming, in process and final release of the products. Manage a team of 20 employees. Coordinate the shipping of sterile products.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

BMorel

Original Signature (electronic, copies or stamps not accepted)

11 Sept 2025

Date

I, Bernarda Cedeno Morel, **certify that as the designated representative for**

Teleflex LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BCM I am at least 21 years of age;
3. BCM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BCM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BCM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BCM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BCM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bernarda Cedeno Morel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11 Sep 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BERNARDA CEDENO MOREL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11 Sep 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, BERNARDA CEDENO MOREL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11 Sep 2025

Date

Subscribed and Sworn to before me this 11th day of Sept 2025

Notary Public Signature

FRANK P. MARINO
Notary Public
Massachusetts
My Commission Expires
Jan 22, 2027

(Seal)

List of employees

First Name	Last Name	Position Title
Abdul	Mayambala	Medical Device Assembler
Abrahan	Rijo	Lead Mechanical Assembler
Adam	Osborne	Production Supervisor
Adol	Mashut	Medical Device Assembler
Adrian	Ortiz	Medical Device Assembler
Alenida	onsalve Zapata Urizar	Medical Assembler 1
Alexia	Casey	Temp-Administrative Assistant
Alexis	Matos Falcon	Facilities Maintenance Technician
Allan	Maina	Test Technician
Amanda	Loch	Line Lead
Amara	Chhaya	Medical Device Assembler
Amelia	Mom	Dip Room Operator
Amine	Zerouali	Maintenance & Facilities Manager
Ana	Moundele	Quality Control Inspector
Ana	Iribe Aviles	Manufacturing Engineer IV
Analiza	Pista	Documentation Specialist
Andrew	Raneri	Medical Assembler 1
Anisha	Khalifa	Medical Device Assembler Operator
Anmol	Nagre	Senior Design Development Manager
Ann Marie	Lamontagne	Medical Assembler 1
Asia	Yang	Medical Device Assembler
Bai	Bangura	Dip Room Operator
Benito	Vazquez	Line Lead
Berkis	Polanco	Medical Device Manufacturing Operator
Bernarda	Cedeno-Morel	Quality Control Manager
Bhavesh	Jani	Medical Device Assembler
Bidur	Badal	Manufacturing Engineer III
Bijalbahen	Patel	Medical Device Assembler
Brailin	Valdez	Medical Assembler 1
Brandon	Lieu	Temp-Tipping Operator
Brenda	Kluck	Test Technician
Bret	Viray	Enterprise Excellence Engineer
Brian	Cannon	Project/Program (Design) Mgmt 5
Bryan	Christie	Temp-Medical Device Assembler
Bunnarin	Bo	Line Lead
Bunthan	Chan	Temp-Test Technician
Carolina	Solano	Medical Assembler 1
Catalina	Jaramillo	QC Inspector
Channary	Moun	Value Stream Supervisor
Channy	Tep	Medical Assembler 1
Chantana	Sok	Medical Assembler 1
Chek	Kong	Temp-Medical Device Assembler
Chhoeu	Nha	Medical Assembler 2

First Name	Last Name	Position Title
Christen	Agnew	Temp-Tipping Operator
Christian	Ortega	Test Technician
Christian	Kabuye	Medical Device Assembler
Christopher	Bell	Mechanical Assembler
Christy	Samba	Medical Device Assembler
Constance	Cross	IABP Assembly Operator
Cristian	Varona Nuñez	Medical Assembler 1
Cristina	Mejia	QC Inspector
Cristina	Liu	Team Lead- Purchasing
Crystal	Som	Medical Device Assembler
Dahiana	Trocoso	Temp-IAB Assembly Operator
David	Morales Rascon	Manufacturing (Industrial) Engineer, IV
David	Boketshu	Value Stream Supervisor
Davide	Tassi	Line Lead
Debra	Vance	Sr. Production Control Coordinator
Delmy	Morales	Medical Device Assembler
Deven	Rashid	Material Handler
Dina	In	line lead
Donald	Dacosta	Line Lead
Donald	Fortin	Medical Device Assembler
Douglas	Bridell	Value Stream Manager
Edwin	Montalvo	Line Lead
Ehku	Hser	Medical Device Assembler
Eileen	Izaguirre	Senior Material Handler
Elizah	Yost	IABP Assembly Operator
Emely	Genao Ramos	Medical Device Assembler
Emily	Brown	Operations Training Leader
Erika	Vaquerano	Group Lead
Eunice	Gomez	Mechanical Assembler
Fabiola	Pacheco	Medical Device Assembler
Fernando	Batista	Tooling Technician
Frank	Kalume	Medical Assembler 1
Frantz	Alexandre	Medical Assembler 1
Gary	Swaim	Documentation Specialist 3
Gemma	Ouellette	QC Inspector
Gennaro	Mom	Manufacturing Technician
George	Cruz	Temp-IAB Assembly Operator
Gloria	Zapata	Medical Assembler 1
Glorisela	Jimenez	Medical Device Assembler
Guadalupe	Pina	Medical Device Assembler
Guang Xing	Huang	Manufacturing Engineering Technician
Hannah	Dobrovolskiy	Human Resources Manager
Ho	Duong	Medical Assembler 1
Holly	Trinh	QC Inspector
Hong	An	Medical Assembler 2
Ismariel	Garcia	Medical Assembler 1

First Name	Last Name	Position Title
Jack	Black	IABP Assembly Operator
Jacob	King	Temp- Medical Device Assembler
James	Cam	Temp-Medical Device Assembler
James	Luraghi	Sr. Manufacturing Engineering Manager
Jamie	Buchannan	Warehouse Manager
Janice	Dill	Medical Device Assembly Operator
Jasmine	Martinez Rodriguez	Medical Device Assembler
Jefna	Dadaille	Medical Device Assembler
Jeniffer	Lugo	Medical Device Assembler
Jennifer	Resto	Medical Device Assembler
Jessika	Jeamaux	Medical Device Assembler
Joanna	Fajardo	Temp-Medical Device Assembler
Jocelyn	Martinez Vega	QC INSPECTOR 2
Jodi	Schrader	Enterprise Excellence Manager
Joelky	Reynoso	Material Handler
Joey	Ouk	Medical Assembler 1
Johanis	Garcia	Temp-Medical Device Assembler
Johnsel	Garcia	Temp-Medical Device Assembler
Jonathan	Maza	Material Handler
Jorge	Martinez-Fernandez	Medical Assembler 1
Jose	Rivera	Medical Device Assembler
Jose	Rivera Roig	Medical Assembler 1
Jose	Araujo Ozuna	Medical Device Assembler
Joseph	Karuri	Temp- Medical Device Assembler
Joshua	Mukandila	Dip Room Operator
Joshua	Nutter	Medical Device Assembler
Jovannie	Ferrer	Material Handler
Juan	Martinez	Test Technician
Juan Isidro	Serrano	Material Handler
Juana	Sanchez	Medical Device Assembler
Julian	Phachansiri	Medical Device Assembler
Julie	Mannorind	Medical Assembler 2
Julie	Rodriguez	Medical Assembler 1
Junyu	Huang	Medical Device Assembler
Justin	Sar	Temp- Medical Device Assembler
Kalvein	Oum	Temp-Medical Device Assembler
Kanchan	Lumb	Line Lead
Katelyn	Matias	Temp-Medical Device Assembler
Kathryn	Licata	Sr. Quality Engineer
Katrina	Nguyen	Temp-Medical Device Assembler
Keaton	Thoeuk	Medical Device Assembler
Kelvin	Martinez	Medical Device Assembler
Kenneth	Twining	EHS Engineer
Kennry	Khiev	QC Inspector
Kenny	Chea	IABP Assembly Operator
Keo	Sokuntheary	Medical Device Manufacturing Operator

First Name	Last Name	Position Title
Kevin	Kong	QC Inspector
Khim	Lim	Value Stream Supervisor
Kimleang	Thon	Medical Assembler 1
Kimunn	Oeung	Line Lead
Korinna	Gouveia	Temp-Medical Device Assembler
Kruti	Vora	Process Development Engineer II
Kupesa	Williams	Temp-Material Handler
Laban	Wanjiku	Medical Device Assembler
Laihieng	Phoeuk	Medical Assembler 2
Lakhena	Lor	Medical Assembler 2
Laura	Vivas Rojas	Line Lead
Leidy	Zapata	Line Lead
Leidy	Lozano	Medical Device Assembler
Leila	Rodriguez	Medical Device Assembler
Liliana	Gonzalez	Temp-Tipping Operator
Lina	Kuch	Medical Assembler 1
Lorena	Marinez	Production Manager
Lourdes	Vincent	Medical Assembler 1
Luis	Ortiz	Medical Assembler 3
Luis	Santana	Medical Device Manufacturing Operator
Lynn	Lain	Medical Device Assembler
Madhuri	Balineni	QC Inspector 1
Maleneth	Leng	QC Inspector
Manuel	Santiago	Medical Device Assembler
manuth	pen	Medical Device Assembler
Marady	Meas	Medical Assembler 1
Maria	Izaguirre	Value Stream Supervisor
Mark	Castiglione	Sr. Site Buyer
Mary	Stone	Medical Device Assembler
Mary Ellen	Mastacouris	Sr Documentation Specialist
Mashal	Noori	Medical Device Assembler
Matilde	Soliman	Medical Assembler 2
Mavrick	Mejia	Manufacturing Maintenance Repair Technician
Melinda	Neang	Medical Assembler 1
Michael	Simard	Mechanical Assembler
Michael	Bahou Jr	Medical Device Assembler
Michael	Morrison	Sr. Materials Manager
Michelle	Douston	Medical Assembler 1
Minaben	Patel	Medical Assembler 1
Minh	Koeun	Medical Device Assembler
Miriam	Gonzalez	Medical Assembler 2
Mom	Try	Medical Device Assembler
Monica	Bou	Temp-Medical Device Assembler
Nancy	Pou	Medical Device Assembler
Natalie	Beng	Medical Assembler 2
Nathanael	Zegarski	Quality Engineer II, Product Quality Assurance

First Name	Last Name	Position Title
Neha	Muttal	Sr. Quality Assurance Engineer
Ngan	Trinh	Medical Device Manufacturing Operator
Nilofar	Salejwala	Medical Device Assembler
Oscar	Jimenez	IABP Assembly Operator
Patrick	Lay	Test Technician
Patrick	Calascibetta	Temp-Dip Room Operator
Paul	Em	Temp-Medical Device Assembler
Paula	Meas	Medical Assembler 2
Pedro	De Aza	Medical Device Assembler
Peter	Cintron	Medical Device Assembler
Peter	Brown	Manufacturing Engineer, III
Phalla	Nou	Temp-Packaging Operator
Phoeurn	Hin	Medical Assembler 1
Phouvieng	Mannorind	Medical Assembler 1
Pichsonita	Tat	Line Lead QC Inspector
Prince	Ntalagana	Medical Device Assembler
Priya	Sampath	Sr. Quality Assurance Manager
Puthavy	Aong	Medical Assembler 2
Raascye	Keo	Temp-Medical Device Assembler
Rachel	Higgins	Quality Engineer, II
Rady	Bou	Medical Assembler 1
Rafael	Rivera	Medical Assembler 2
Rahul Reddy	Sangabathula	Manufacturing Engineer II
Ramiz	Khalifa	Medical Device Assembler
Raquel	Veras	Line Lead
Ratana	Thon	Medical Assembler 1
Recarlo	Blackman	Manufacturing Support Specialist
Ricky	Khampannha	Test Technician
Ritha	Sam	Test Technician
Robin	McClarney	Quality Systems Manager
Ronald	Kiggundu	Mechanical Assembler
Ronaldo	Ribeiro Rua	Medical Device Assembler
Rosemary	Mukai	Medical Device Assembler
Rotha	Hay	Manufacturing Technician
Rotha	Meas	Quality Inspector
Rushikesh	Bhagat	Line Lead
Sabera	Gafur	Medical Assembler 1
Salimbhai	Khalifa	Medical Assembler 1
Samira	Pocha	Medical Device Assembler
Sandra	Leonardo-Marin	Medical Assembler 1
Santos	Gutarra Morales	Medical Assembler 1
Saqib	Jalees	Sr. Process Development Engineer
Saram	Chum	Medical Device Assembler
Sareth	Chann	Medical Assembler 2
Savady	Vann	Medical Device Assembler
Savanna	Mckay	Temp- Medical Device Assembler

First Name	Last Name	Position Title
Scott	Moschella	Manager, IABP Operations Everett
Seang	Khan	Medical Assembler 2
Sereimongkol	Sy	Test Technician
Setha	Keo	Test Technician
Seyha	Oeng	Medical Device Assembler
Shakayla	Wright	Temp-Dip Room Operator
Shanawaz Pasha	Mohammed	Manufacturing Engineer II
Sherri	DiGiovanni	QC Inspector
Shilpi	Verma	Dip Room Operator
Shivani	Patel	Temp-Medical Device Assembler
Shobhana	Patel	Calibration Technician
Simon	Dolera	IABP Mechanical Assembly Operator
Sineth	Deth	Lead Test Technician
Sinthy	Nou	Medical Assembler 2
Sitha	Nhim	Medical Assembler 2
Sivchou	Chhiv	Medical Assembler 2
Smita	Patel	Medical Assembler 1
Soan	Leng	Medical Assembler 1
Socheata	Uong	Medical Assembler 1
Socheath	Heyl	Medical Assembler 1
Sodavin	Phat	Medical Device Assembler
Sodie	San	Manufacturing Technician
Sofia	Rodriguez	Medical Assembler 1
Sol	Pen	IABP Assembly Operator
Sombo	Sorng	Medical Device Assembler
Sopheany	Thon	Line Lead
Sophoas	In	Medical Assembler 1
Sophorn	Van	Material Handler
Sorithyvong	Mey	Medical Device Assembler
Sotheany	Ven	Medical Assembler 1
Sovan	Chhoy	Medical Device Assembler
Sovanndara	Neang	Medical Assembler 1
Sovichea	Kheang	Medical Assembler 2
Spesioza	Moriasi	Temp-Medical Device Assembler
Srey Pech	Phat	Medical Device Assembler
Sreyleak	Song	QC Inspector
Sreypao	Suy	Medical Device Assembler
Stephen	Jansen	Mechanical Assembler
Steven	Helser	Plant Manager
Susan	Sum	Medical Assembler 1
Ta	Ry	Medical Device Assembler
Tamara	Salazar	Line Lead
Tea	Sinkler	Temp-Molding Operator
Thanareth	Sarith	Material Handler
Thanh	Doan	Medical Assembler 2
Theard	Jourdan	Stockroom Lead

First Name	Last Name	Position Title
Theary	Lim	Medical Assembler 1
Theng Hong	Lay	IABP Assembly Operator
Thida	Pheng	Line Lead
Thoeun	Nhet	Temp-IAB Assembly Operator
Timothy	Seng	Medical Device Assembler
Tina	Kuy	Medical Device Assembler II
Tony	Dinh	QC Inspector
Tony	Chan	Senior Manufacturing Planner
Vanny	Hang	Medical Device Assembler
vanthon	huy	Medical Device Assembler
Varshaben	Patel	Medical Assembler 1
Vasant	Patel	Medical Assembler 1
Vathana	Sap	Line Lead QC Inspector
Visith	Dou	Test Technician
Vuon	Lieu	Inside Technical Service Supervisor
Wilfrido	Ortiz	Material Handler
William	Singleton	Electrical Engineer
William	Burns	Manufacturing Engineering, III
Yansel	Garcia	Temp-Medical Device Assembler
Yenifer	Paulino	Medical Device Assembler
Yong	Chan	Medical Assembler 1
Yonsaktyna	Keo	Medical Device Assembler
Yosary	Joga Nunez	Medical Assembler 1
Zawadi	Atanga	Medical Assembler 1

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH01856	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Teleflex LLC

Physical Address: 11245 North Distribution Cove

City: Olive Branch State: MS Zip: 38654

Mailing Address (if different from physical address): 3015 Carrington Mill Blvd

City: Morrisville State: NC Zip: 27560

Telephone: 662-892-6100 Website: https://teleflex.com

Name of Designated Representative (DR): Jimmy Breedlove

Licensing Company Email: statelicensing@teleflex.com DR Email: jimmy.breedlove@teleflex.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: wholesaler, distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Huons
Address: 901 Pangyo Innovalley City: Seongnam-Si South Korea State: _____ Zip: _____

Name: Spectra
Address: 299 Ballardvale Street City: Wilmington State: MA Zip: 01887

Name: Pfizer
Address: 275 M Field Drive Lake City: Lake Forest State: IL Zip: 60045

Name: _____
Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____
Parent Company (if any): _____
Corporation Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Teleflex Logistics LLC
Corporation/Organization Name: Teleflex LLC
Mailing Address: 3015 Carrington Mill Blvd
City: Morrisville State: NC Zip: 27560
Telephone: 919-544-8000 Email: statelicensing@teleflex.com
Contact Person Name: Matthew Howald

Section 6: Partnership

Partnership Name: _____
Mailing Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____
Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____
Business Name: _____
Business Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Teleflex LLC

Facility Name

Jacob Newman

Print Name of Authorized Person Submitting Application

Jacob Newman

Original signature of Authorized Person (copies or stamps not accepted)

10/6/25

Date

Board Use Only	Date Received: _____	Amount: _____

NABP ACCREDITED
DRUG DISTRIBUTOR

Teleflex LLC

located at

11245 North Distribution Cove, Olive Branch, MS 38654

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/15/2023 - 12/14/2026
Period of Accreditation

FIFTH AMENDED AND RESTATED LIMITED LIABILITY COMPANY AGREEMENT

OF

TELEFLEX LLC

This Fifth Amended and Restated Limited Liability Company Agreement of Teleflex LLC is effective as of May 20, 2025 (the "***Effective Date***").

RECITALS

A. Teleflex LLC, a Delaware limited liability company (the "***Company***"), was formed by Teleflex Incorporated (the "***Initial Member***") on August 20, 2018 (the "***Formation Date***") by the filing of the certificate of formation of the Company (as amended from time to time, the "***Certificate***") with the Office of the Secretary of State of the State of Delaware.

B. Prior to the Effective Date, the Initial Member was the sole member of the Company and the Company was governed pursuant to the terms and provisions of that certain Limited Liability Company Agreement of Teleflex LLC dated August 20, 2018.

C. On February 21, 2020, Teleflex Life Sciences Limited, a company formed and existing under the laws of Malta, having its registered office at 171, Old Bakery Street, Valletta, VLT 1455, Malta, and registered with the Malta Business Registry under registration number C94305 ("***TLS***"), acquired the Initial Member's Interest in the Company and became a member of the Company (the "***TLS Acquisition***").

D. Following the Acquisition, the Company issued an additional Interest in the Company to Teleflex General Partner LLC, a Delaware limited liability company ("***TGP***"), the Company was governed pursuant to the terms and provisions of that certain Amended and Restated Limited Liability Company Agreement of Teleflex LLC dated February 21, 2020, and TLS and TGP were the members of the Company.

E. On December 15, 2023, TLS assigned and transferred its 99.999% Interest in the Company to Teleflex Medical Devices LLC, a Delaware limited liability company ("***TMD***"), and TMD was admitted as a member of the Company, together with TGP, and the Company was governed pursuant to the terms and provisions of that certain Second Amended and Restated Limited Liability Company Agreement of Teleflex LLC dated December 15, 2023.

F. On December 16, 2023, TMD assigned and transferred its 99.999% Interest in the Company to Teleflex Technologies LLC, a Delaware limited liability company ("***TTech***" or and TTech was admitted as a member of the Company, together with TGP, and the Company was governed pursuant to the terms and provisions of that certain Third Amended and Restated Limited Liability Company Agreement of Teleflex LLC dated December 16, 2023.

G. On December 18, 2023, TGP merged with into TTech and as a result of the merger, TTech became the sole member of the Company.

H. On December 19, 2023, TTech filed a certificate of amendment with the Delaware Secretary of State and changed its name to Teleflex Life Sciences II LLC ("***TLS II***"), and the Company was governed pursuant to the terms and provisions of that certain Fourth Amended and Restated Limited

Liability Company Agreement of Teleflex LLC dated December 19, 2023 (the "***Prior Agreement***") with TLS II as its sole member following the name change and merger.

I. On May 20, 2025 TLS II assigned and transferred its entire Interest in the Company to Teleflex Logistics LLC, a Delaware limited liability company ("***Teleflex Logistics***" or the "***Member***").

Teleflex Logistics, as the sole Member of the Company following the assignment, desires to amend and restate the Prior Agreement in its entirety to provide for the terms and provisions relating to its ongoing ownership and management of the Company.

Accordingly, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS

Capitalized terms used but not otherwise defined in this agreement have the meanings given to those terms in Exhibit A.

ARTICLE II
GENERAL PROVISIONS

2.1 Formation of Limited Liability Company

The Company was formed as a Delaware limited liability company on the Formation Date by the filing of the Certificate with the Office of the Secretary of State of the State of Delaware under and pursuant to the Act. The Board will file or cause to be filed all such other certificates, notices, statements, amendments or other instruments required by law for the continued operation of the Company as a limited liability company.

2.2 Name of Company

The name of the Company is "Teleflex LLC." The business of the Company may be conducted under any name chosen by the Member, and the Member may, in its sole discretion consistent with the requirements of the Act, change the name of the Company from time to time.

2.3 Principal Place of Business; Registered Agent for Process

(a) The principal office of the Company will be at such place as the Member may designate, in its sole discretion, from time to time.

(b) The registered office of the Company in the State of Delaware will be at such place as the Member may designate, in its sole discretion, from time to time. The registered agent of the Company in the State of Delaware to accept service of process will be such Person as the Member may designate, in its sole discretion, from time to time.

2.4 Term of Company

The term of the Company commenced on the date the Certificate was filed in the office of the Secretary of State of the State of Delaware in accordance with the Act and will continue until terminated pursuant to Section 9.1.

2.5 Purposes

The Company is organized for the purpose of carrying on any lawful business, as determined appropriate by the Board. Notwithstanding the preceding sentence, the Company may execute and deliver and perform all contracts and other undertakings and engage in all the activities and transactions that may, in the opinion of the Board, be necessary or advisable to carry out the foregoing purposes, subject to the limitations contained in this agreement and the Act. The Board shall cause the Company to be qualified or registered under applicable laws of any jurisdiction in which the Company transacts business and shall be authorized to execute, deliver and file any certificates and documents necessary to effect such qualification or registration, including without limitation the appointment of agents for service of process in such jurisdictions.

2.6 Title to Company Property

All property owned by the Company is to be deemed to be owned by the Company as an entity, and the Member will not have any direct ownership interest in any such property.

2.7 Failure to Observe Formalities

A failure to observe any formalities or requirements of this agreement, the Certificate or the Act will not be grounds for imposing personal liability on the Member or the Managers for liabilities of the Company.

2.8 No Partnership Intended for Nontax Purposes

The Member has formed the Company under the Act, and expressly denies any intent hereby to form a partnership or a corporation under applicable law.

2.9 Liability of the Member to Third Parties; No Reliance by Third-Party Creditors

(a) Except as otherwise provided in the Act, the Member will not be personally liable for any debt, obligation or liability of the Company, whether arising in contract or otherwise, by reason of being a member of the Company.

(b) This agreement is entered into by the Member for the exclusive benefit of the Member and their successors and assigns. This agreement is expressly not intended for the benefit of any creditor of the Company or any other Person. Except and only to the extent provided by applicable statute, no such creditor or third party has any rights under this agreement or any agreement between the Company and the Member with respect to any contributions or otherwise.

2.10 Fiscal Year

The fiscal year of the Company shall begin on January 1st and end on December 31st, provided that the initial fiscal year of the Company shall begin as of the Formation Date.

2.11 Functional Currency

The functional currency of the Company shall be United States Dollars.

ARTICLE III
MEMBER

3.1 Member

The Company is owned exclusively by the Member pursuant to the terms of this agreement. In the event the Company has more than one Member, this agreement will have no further force and effect. No Interest in the Company shall be represented by a separate certificate.

3.2 Capital

The Member may (but is not required to) contribute capital to the Company in such amounts and at such times as it may determine in its discretion.

ARTICLE IV
ALLOCATION OF NET INCOME AND NET LOSS

All items of Net Income or Net Loss will be allocated exclusively to the Member.

ARTICLE V
DISTRIBUTIONS

Net Cash Flow and Company assets in kind will be distributed in such amounts, and at such times as the Board may in its absolute discretion determine. Any such distribution will be made exclusively to the Member.

ARTICLE VI
MANAGEMENT

6.1 Management Vested in the Board of Managers

As provided and subject to the terms herein, a board of Managers (the "***Board***") has the authority to manage the business and affairs of the Company. Any action required to be taken by the Board will be duly taken if approved, in writing or otherwise, by the Board as required by the terms of this agreement.

6.2 Composition of Board

6.1.1 Number of Managers

The Board will be composed of three (3) Managers, who are specified in Section 6.2.2. The number of Managers may be changed by the Member from time to time.

6.2.2 Appointment of Managers

As of the Effective Date, the Managers are John Deren, Mikhail Kryukov and Matthew Howald.

6.2.2 Term of Managers

Each Manager will hold office until such Manager dies, resigns or is otherwise removed pursuant to Section 6.2.2. Any Manager may resign at any time by delivering written notice to the Member. Any such resignation will be effective upon delivery thereof unless the notice of resignation specifies a later effective date. The acceptance of such resignation by the Member will not be necessary to make it effective.

6.2.3 Removal of Manager

A Manager may be removed with or without cause at any time by the unanimous written consent of the Member.

6.2.4 Filling a Vacancy

Any vacancy occurring on the Board is to be filled by an appointee as designated by the Member. The term of any replacement Manager will extend to the remainder of the term of the departed Manager.

6.3 Manner of Acting

The act of a majority of the number of Managers (whether by vote at a meeting of the Board or by written consent) will be the act of the Board, unless the vote of a greater number is required by this agreement, the Certificate or the Act.

6.4 Compensation

Unless approved by the Member, the Managers will not be paid any compensation in connection with their service as a Manager. Notwithstanding the preceding sentence, no Manager is precluded from serving the Company in any other capacity and receiving compensation therefor.

6.5 Authority of the Board

6.4.1 Authority of the Board

Except as otherwise provided herein, the Board is vested with complete management and control of the affairs of the Company, except to the extent that the Board delegates authority to one or more Officers or other Persons designated by the Board. Except as otherwise provided herein, the Manager has the power and authority to do all things necessary or proper to carry out the purposes of the Company. All actions taken by the Board will be subject to the terms of this agreement. In their capacity as Managers, the Managers are specifically authorized to execute authorized instruments, documents, agreements, contracts and other undertakings on behalf and in the name of the Company, and parties dealing with the Company are entitled to rely on the authority of each Manager to execute such documents on behalf of the Company. In addition, the Board may delegate to one or more Persons the authority to execute authorized instruments, documents, agreements, contracts and other undertakings on behalf and in the name of the Company.

6.4.2 Limitation on Authority of the Board

The Board, without the unanimous written consent of the Member, has no authority to:

(a) cause the issuance or sale of any additional Interests in the Company;

(b) amend this agreement;

(c) effect a merger of the Company or the sale, lease, exchange or other disposition of all, or substantially all, the Company's property, or any other similar business combination pursuant to which any Interest of the Company is converted into or exchanged for cash, securities or other property of an acquiring entity or any of its affiliates; provided that the Board may effect such a transaction that only involves the Company and one or more other entities part of the Teleflex Incorporated commonly controlled group of companies without prior written consent of the Member;

(d) cause the Company to acquire any business by sale, lease, assignment or other transfer or conveyance of assets, property or securities or by merger or other form of business combination or otherwise, or make any agreement or become obligated to do so;

(e) do any act that would contravene this agreement;

(f) do any act that would make it impossible to carry on the ordinary business of the Company; or

(g) possess Company property, or assign rights in Company property, for other than a Company purpose.

6.6 Obligations of Managers

Each Manager is to devote such business time to the Company as may be reasonably necessary to manage the affairs and activities of the Company.

6.7 Payment and Reimbursement of Expenses

The Company will reimburse the Managers and the Member for all reasonable expenses incurred by them on behalf of the Company, including without limitation attorneys' fees, filing fees, and other expenses and charges incurred, and that may be incurred, in connection with the formation of the Company.

ARTICLE VII
OFFICERS

7.1 Authority to Delegate to Officers

The Board has the power and authority to appoint Officers of the Company. Officers have such authority, perform such duties and hold office for such period as may be prescribed by the Board. The Board may delegate to any Officer the power to appoint any subordinate Officers and to prescribe their respective terms of office, authority and duties. Any two or more offices may be held by the same Person.

Unless an Officer dies, resigns or is removed from office, he or she will hold office until his or her successor is appointed.

7.2 Resignation or Removal

Any Officer of the Company may resign from such position by delivering written notice of the resignation to the Board. Any Officer may be removed by the Board, with or without cause, upon receiving written notice from the Board. Election or appointment of an Officer will not of itself create any contractual right to continued employment, compensation or other benefit from the Company. Vacancies in any office caused by any reason may be filled by the Board by selecting an individual to act during the unexpired term.

7.3 Salaries

The compensation of any Officers, agents or other employees of the Company is to be fixed by the Board, and may be changed from time to time by the Board.

7.4 Signing Authority

The Board may authorize any Officer or Officers, or agent or agents, to enter into any contract or execute and deliver any instrument in the name of and on behalf of the Company. Such authority may be general or confined to specific instances. All checks, drafts or other orders for the payment of money, notes or other evidences of indebtedness issued in the name of the Company may be signed by such Officer or Officers, or agent or agents, of the Company as is from time to time determined by the Board and in such manner as is from time to time determined by the Board.

7.5 Appointment of Officers

As of the Effective Date, the Officers of the Company are as follows:

- Mikhail Kryukov, Vice President & Secretary
- Matthew Howald, Vice President & Treasurer; and
- John R. Deren, President.

ARTICLE VIII
INDEMNIFICATION

8.1 Limitation on Liability

No Member, Manager or Officer, or employee, shareholder, member, partner, delegate or agent thereof, will be liable, responsible or accountable in damages or otherwise to the Company or the Member for any act or omission by any such Person if such Person acted in good faith and in a manner in which he, she or it believed to be in the best interests of the Company unless such conduct constitutes fraud, gross negligence, willful misconduct or a material breach of this agreement.

8.2 Indemnification

To the fullest extent not prohibited by law, the Company will indemnify and hold harmless the Member, each Manager and each Officer, and each employee, shareholder, member, partner, delegate or agent thereof, from and against any and all losses, claims, demands, costs, damages, liabilities (joint and several), expenses of any nature (including without limitation attorneys' fees and disbursements), judgments, fines, settlements and other amounts arising from any and all claims, demands, actions, suits or proceedings, civil, criminal, administrative or investigative, in which such Person may be involved or threatened to be involved, as a party or otherwise, arising out of or incidental to any business of the Company transacted or occurring while such Person was a member, Manager or Officer, or employee, shareholder, member, partner, delegate or agent thereof, regardless of whether such Person continues in such capacity at the time any such liability or expense is paid or incurred, except for fraud, gross negligence, willful misconduct or bad faith on the part of such Person. The indemnification provided by this Section 8.2 will be in addition to any other rights to which those indemnified may be entitled under any agreement, as a matter of law or equity, or otherwise, and will continue as to a Person who has ceased to serve in their capacity, and will inure to the benefit of the heirs, successors, assigns and administrators of the Person so indemnified. With respect to the satisfaction of any indemnification of the above-mentioned Persons, only assets of the Company will be available therefor and the Member will not have any personal liability therefor. Any indemnification required hereunder to be made by the Company will be made promptly after the liability, loss, damage, cost or expense is incurred or suffered. The Board may establish reasonable procedures for the submission of claims for indemnification pursuant to this Section 8.2, determination of the entitlement of any Person thereto and review of any such determination.

8.3 Advancement of Expenses

The right to indemnification conferred in this Article VIII includes the right to be paid by the Company the expenses incurred in defending any proceeding in advance of its final disposition. An advancement of expenses must be made upon delivery to the Company of an undertaking, by or on behalf of such indemnitee, to repay all amounts so advanced if it is ultimately determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses under this Section 8.3.

ARTICLE IX
DISSOLUTION AND TERMINATION

9.1 Events of Dissolution

(a) The Company may be dissolved on a date designated by the Member.

(b) Subject to the foregoing, the death, retirement, resignation, expulsion, bankruptcy or dissolution of a Member or the occurrence of any other event that terminates the continued membership of a Member will not cause the Company to be dissolved or its affairs to be wound up, and upon the occurrence of any such event, the limited liability company will be continued without dissolution.

9.2 Effectiveness of Dissolution

Dissolution of the Company will be effective on the date on which the event occurs giving rise to the dissolution, but the Company may not terminate until the assets of the Company have been

distributed as provided herein. Notwithstanding the dissolution of the Company, prior to the termination of the Company, as aforesaid, the business of the Company and the affairs of the Member, as such, will continue to be governed by this agreement. Upon dissolution, the Member must cause the assets of the Company to be liquidated and must cause the proceeds thereof to be applied and distributed as contemplated by this agreement.

9.3 Distributions Upon Liquidation

Distributions upon liquidation of the Company, after payment to all creditors, are to be made to the Member.

ARTICLE X
BOOKS, RECORDS AND BANK ACCOUNTS

10.1 Books and Records

(a) The books and records of the Company will be maintained at the principal office of the Company.

(b) The Company will maintain with its books and records the following: (1) a current list of the full name and last known address of the Member; (2) a copy of the Certificate, and all certificates of amendment thereto; (3) copies of the Company's federal, state and local tax returns and reports, if any, for the three most recent fiscal years; (4) copies of this agreement and any amendments thereto; and (5) copies of all financial statements for the Company for the three most recent fiscal years.

10.2 Bank Accounts

The Board is responsible for causing one or more accounts to be maintained in a bank (or banks), as necessary, which accounts are to be used for the payment of expenditures incurred in connection with the business of the Company, and in which are to be deposited any and all cash receipts. All such amounts are to be received, held and disbursed by the Company for the purposes specified in this agreement. There may not be deposited in any of such accounts any funds other than funds belonging to the Company, and no other funds will in any way be commingled with such funds.

ARTICLE XI
MISCELLANEOUS

11.1 Successors and Assigns

This agreement, and each and every provision hereof, will be binding on and will inure to the benefit of the Member, their respective successors, heirs, successors in title and assigns, and each and every successor in interest to any Member, whether such successor acquires an Interest by way of gift, purchase, foreclosure or by any other method, will hold such Interest subject to all the terms and provisions of this agreement.

11.2 Amendment of Agreement

Except as otherwise provided herein, this agreement may be amended only upon the unanimous written consent of the Member.

11.3 Captions

Titles or captions of articles or sections contained in this agreement are inserted only as a matter of convenience and for reference, and in no way define, limit, extend or describe the scope of this agreement or the intent of any provisions hereof.

11.4 Applicable Law

This agreement and the rights and obligations of the parties hereunder are to be governed by and interpreted, construed and enforced in accordance with the laws of the State of Delaware (regardless of the choice of law principles of the State of Delaware or of any other jurisdiction).

11.5 Severability

If any provision of this agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the provisions shall remain in full force and effect and shall in no way be affected, impaired or invalidated.

Docusign Envelope ID: 8D1058E8-20CC-4EC1-AF11-7FDD50B2F4C8

The Member has executed this Fifth Amended and Restated Limited Liability Company Agreement as of the Effective Date.

MEMBER:

TELEFLEX LOGISTICS LLC

DocuSigned by:
Matt Howald
74CDEFA2F47641C...

By: Matthew Howald
Its: Manager

EXHIBIT A

DEFINITIONS

Capitalized terms used in this agreement have the following meanings:

"***Act***" means the Delaware Limited Liability Company Act, as amended from time to time.

"***Interest***" means the entire ownership interest of a Member in the Company at any particular time, including without limitation the right of such Member to any and all benefits to which such Member may be entitled as provided in this agreement, together with the obligations of such Member to comply with all the terms and provisions of this agreement.

"***Member***" means Teleflex Logistics LLC and any other Person that may be admitted as a member of the Company subsequent to the Effective Date, in each case in their capacity as a member of the Company and for so long as they remain a member of the Company.

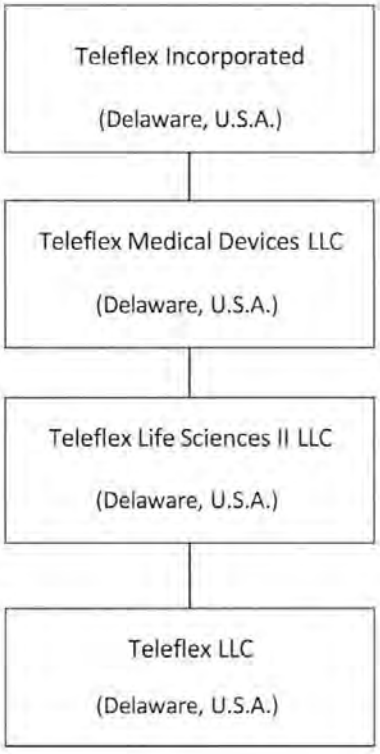
"***Net Cash Flow***" means, for each fiscal year or other period, the gross cash proceeds received by the Company for such year or period, less cash expenditures of the Company for such year or period, less reserves for future Company expenditures as determined by the Member.

"***Net Income***" and "***Net Loss***" mean, for each fiscal year or other period, an amount equal to the Company's realized and unrealized net income or net loss for such fiscal year or other period.

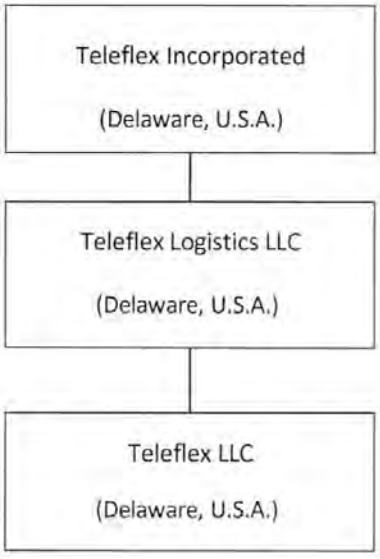
"***Officer***" means a Person designated or appointed as an officer of the Company pursuant to Article VII.

"***Person***" means any individual, corporation, partnership, trust, limited liability company or other entity.

Teleflex LLC
2024



Teleflex LLC
2025



Teleflex®

Teleflex

3015 Carrington Mill Blvd
Morrisville, NC 27560
USA
Phone: 919-361-4150
Fax: 919-361-3905

teleflex.com

January 13, 2026

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

Subject: Change of Officer for licenses # WH01856 Teleflex LLC in MS
WH03764 Teleflex LLC in MA

To Whom It May Concern,

Please find attached the updated document regarding the Officer of Teleflex LLC

Please feel free to contact me using the information below if you have questions or concerns.

Kind regards,

Bettina Knight

Bettina Knight
State Licensing Lead

Teleflex

OFFICERS OF TELEFLEX LLC

OFFICERS	*TITLE*
Jake Newman jake.newman@teleflex.com ***Manager*	*President*
Daniel Logue daniel.logue@teleflex.com ***Manager*	*Vice President & Secretary*
Marina Zivik Marina.zivik@teleflex.com ***Manager*	*Vice President*
Matthew Howald matt.howald@teleflex.com ***Manager*	*Vice President, & Treasurer*

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TELEFLEX LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF MAY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TELEFLEX LLC" WAS FORMED ON THE TWENTIETH DAY OF AUGUST, A.D. 2018.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7023120 8300

SR# 20252281803

Authentication: 203691441

Date: 05-14-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **TELEFLEX LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/05/2019, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 10/20/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202510206193242
You may verify this certificate online at https://www.nvsilverflume.gov/home

MISSISSIPPI BOARD OF PHARMACY

LICENSE VERIFICATION

The Mississippi Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

Teleflex LLC

Medical Gas Wholesaler

Permit Status:	Active	**Issued Date:**	01/21/2015	**Discipline on File:**	No
Permit #:	14181	**Effective Date:**	05/30/2025		
Manager Name:	Jimmy Breedlove	**Expire Date:**	12/31/2027	**Discipline Status:**	No Discipline
				Address:	Teleflex LLC 11245 North Distribution Cove Olive Branch, MS 38654

Controlled Substance Registration

No controlled substance registration found!

Public Records

No disciplinary documents were found!

Information loaded from this database is current as of 1/15/2026 5:41:53 PM

MISSISSIPPI BOARD OF PHARMACY

LICENSE VERIFICATION

The Mississippi Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

Teleflex LLC

Drug Facility

Permit Status:	Active	**Issued Date:**	03/02/2017	**Discipline on File:**	No
Permit #:	15198	**Effective Date:**	10/21/2025	**Discipline Status:**	No Discipline
Classification:	Wholesale Distributor (In-State)	**Expire Date:**	12/31/2026	**Address:**	11245 North Distribution Cove Olive Branch, MS 38654
Manager Name:	Jimmy Breedlove				

Controlled Substance Registration

No controlled substance registration found!

Public Records

No disciplinary documents were found!

Information loaded from this database is current as of 1/15/2026 5:23:26 PM

MEMORANDUM OF INSURANCE | **DATE** 28-Aug-2025

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of Marsh is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://marshdigital.marsh.com/marshconnect/viewMOI.action?clientId=582422257. The information contained herein is as of the date referred to above. Marsh shall be under no obligation to update such information.

PRODUCER	COMPANIES AFFORDING COVERAGE
Marsh USA LLC ("Marsh")	Co. A Travelers Property Casualty Company of America
INSURED Teleflex Incorporated and Subsidiaries 550 E. Swedesford Road Suite 400, Wayne Pennsylvania 19087 United States	Co. B Travelers Casualty & Surety Company
	Co. C Columbia Casualty Company
	Co. D
	Co. E
	Co. F

COVERAGES

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS MEMORANDUM MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS

CO LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE DATE	POLICY EXPIRATION DATE	LIMITS (LIMITS IN USD UNLESS OTHERWISE INDICATED)	
A	GENERAL LIABILITY Commercial General Liability Occurrence	TJGLSA2J706154TIL25	01-Sep-2025	01-Sep-2026	GENERAL AGGREGATE	2,000,000
					PRODUCTS - COMP/OP AGG	Excluded
					PERSONAL AND ADV INJURY	1,000,000
					EACH OCCURRENCE	1,000,000
					FIRE DAMAGE (ANY ONE FIRE)	1,000,000
					MED EXP (ANY ONE PERSON)	5,000
A	AUTOMOBILE LIABILITY Any Auto Hired Autos Non-Owned Autos	TJCAP2J706166TIL25	01-Sep-2025	01-Sep-2026	COMBINED SINGLE LIMIT	2,000,000
					BODILY INJURY (PER PERSON)	
					BODILY INJURY (PER ACCIDENT)	
					PROPERTY DAMAGE	
A	EXCESS LIABILITY Other than Umbrella Form	EX6S79096125NF	01-Sep-2025	01-Sep-2026	EACH OCCURENCE	10,000,000
					AGGREGATE	10,000,000
A	WORKERS COMPENSATION / EMPLOYERS LIABILITY THE PROPRIETOR / PARTNERS / EXECUTIVE OFFICERS ARE Included	UB8N3139892551K (AOS)	01-Sep-2025	01-Sep-2026	WORKERS COMP LIMITS	Statutory
B		UB8N3113332551R (Retro)	01-Sep-2025	01-Sep-2026	EL EACH ACCIDENT	1,000,000
					EL DISEASE - POLICY LIMIT	1,000,000
					EL DISEASE - EACH EMPLOYEE	1,000,000

C	Primary Products Liability - Clinical Trials	ADT2091141649	01-Sep-2025	01-Sep-2026	Each Claim / Aggregate: 15,000,000 / 15,000,000

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications here to are not authorized.

MEMORANDUM OF INSURANCE | **DATE** 28-Aug-2025

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PRODUCER
Marsh USA LLC
("Marsh")

INSURED
Teleflex Incorporated and Subsidiaries
550 E. Swedesford Road
Suite 400, Wayne
Pennsylvania 19087
United States

ADDITIONAL INFORMATION
ADDITIONAL INFORMATION
Provisions that we can include upon request:
Automobile
1. Broad Named Insured
2. Employees as Insureds
3. Additional Insured Lessor and Loss Payee as Required by Written Contract.

Workers Compensation:
1. Waiver of Subrogation as Required by Written Contract

General Liability and Premises Operations:
1. Broad Named Insured
2. Blanket Additional Insured as Required by Written Contract
3. Waiver of Subrogation as Required by Written Contract

Products Liability:
1. Worldwide Coverage Territory
2. Vendors are included as insureds as required by written contract
3. See key policy definition of Insured Product below
Note:
Excess Liability applies over General Liability, Automobile Liability and Employers Liability.

CNA policy definition of Insured Product
INSURED PRODUCT
Insured product means any goods or products:
A. manufactured, developed, designed, created, or tested;
B. sold, leased, licensed, rented, handled, marketed, distributed to others; or
C. disposed of;
by the Insured Entity or others on the Insured Entitys behalf, including but not limited to:
1. biological products, pharmaceutical drugs, medical devices, nutraceuticals; or
2. products that are used, or are intended for use in clinical trials, health care or the providing of

professional services; or
3. containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products.
Insured product includes:
a. warranties or representations made at any time with respect to the fitness, quality, durability, performance, use, handling, operation or safety of insured product; and
b. the providing of or failure to provide warnings or instructions.

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications hereto are not authorized.

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800052326

Application/License No. _____

Teleflex LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 11245 North Distribution Cove, Olive Branch, MS 38654 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800, Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 19, 2019 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of September, 2019.

APPLICANT/PRINCIPAL

Teleflex LLC

Authorized Representative

SURETY COMPANY

Atlantic Specialty Insurance Company

Surety Company's Representative

Adanna Brathwaite, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Adanna Brathwaite, Nevada Non-Resident Agent

OneBeacon
INSURANCE GROUP

Power of Attorney

Surety Bond No: 800052326

Principal: Teleflex LLC

Obligee: Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Minnetonka, Minnesota, does hereby constitute and appoint: Adanna Brathwaite, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **sixty million dollars ($60,000,000)** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this eighth day of December, 2014.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNIPEN COUNTY

On this eighth day of December, 2014, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

SA LESHA V. S. BEEKS
Notary Public
State of Minnesota
My Commission Expires
January 31, 2020

_____
Notary Public

I, the undersigned, Assistant Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 19th day of September, 2019.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
James G. Jordan, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Teleflex LLC MDEG License # (if applicable) MP01280

Physical Address 11245 North Distribution Cove

City Olive Branch State MS Zip 38654

Mailing Address (if different from physical address) 3015 Carrington Mill Blvd

City Morrisville State NC Zip 27560

Telephone 662-892-9100 Website https://www.teleflex.com

Licensing Company Email statelicensing@teleflex.com

Section 2: Personal Information

First Jimmy Middle _____ Last Breedlove

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 11245 North Distribution Cove

City Olive Branch State MS Zip 38654

Telephone [redacted] Email jimmy.breedlove@teleflex.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Northwest Mississippi Community College				
Address		City	State	Zip
8750 Deerfield Road		Olive Branch	MS	38654
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Southeast Lauderdale Highschool			1995-1999	
Address		City	State	Zip
2362 Lons Creek Road		Meridian	MS	9301
Diploma/Degree obtained, if any				
highschool diploma				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Addre	City	State	Zip
6/2017 - present	[redacted]	[redacted]	MS	[redacted]
From - To (MM/YY – MM/YY)	Addre	City	State	Zip
2010 - 05/2017	[redacted]	[redacted]	MS	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Teleflex LLC			08/2019-02/2025	
Business Address		**City**	**State**	**Zip**
11245 North Distribution Cove		Olive Branch	MS	38654
Phone	**Title**		**Number of Employed Hours**	
662-892-9100	Operations Manager		20,000	
Description of Duties				
Review labor utilization and personnel performance to ensure a high level of efficiency to meet daily order fulfillments. Provide guidance and direction in solving departmental problems, improvements and document performance.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

20 Oct 2025
Date

I, Jimmy Breedlove, **certify that as the MDEG Administrator for** Teleflex LLC,

that I (initial that you have read and meet the following requirements):

1. JB Have a high school diploma or its equivalent;
2. JB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jimmy Breedlove
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

20 OCT 2025
Date

Board Use Only	Date Received: 10/27/25

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Teleflex LLC
Pharmacy/Wholesaler License # (if applicable): WH01856 and MP01280
Physical Address: 11245 North Distribution Cove
City: Olive Branch State: MS Zip: 38654
Mailing Address (if different from physical address): 3015 Carrington Mill Blvd
City: Morrisville State: NC Zip: 27560
Telephone: 919 544 8000 Website: https://www.teleflex.com
Licensing Company Email: statelicensing@teleflex.com

Section 2: Personal Information

First: Jimmy Middle: Dale Last: Breedlove
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Address: 11245 North Distribution Cove
City: Olive Branch State: MS Zip: 38654
Telephone: [redacted] Email: jimmy.breedlove@teleflex.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northwest Mississippi Community College			
Address	City	State	Zip
8750 Deerfield Road	Olive Branch	MS	38654
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Southeast Lauderdale Highschool		1995-1999	
Address	City	State	Zip
2362 Lons Creek Road	Meridian	MS	39301
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2017 - present	[redacted]	[redacted]	MS	[redacted]
From - To (MM/YY – MM/YY)			State	
2010 -5/2017			MS	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Teleflex LLC			08/2019 - 02/2025
Business Address	**City**	**State**	**Zip**
11245 North Distribution Cove	Olive Branch	MS	38654
Phone	**Title**	**Number of Employed Hours**	
662-892-9100	Operations Manager	20,000	
Description of Duties			
Review labor utilization and personnel performance to ensure a high level of efficiency to meet daily order fulfillments, Provide guidance and direction in solving departmental problems, improvements and document performance.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

J.B.

09 Sep 2025

Original Signature (electronic, copies or stamps not accepted)

09 Sep 2025

Date

I, Jimmy Breedlove, **certify that as the designated representative for**

Teleflex LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JB I am at least 21 years of age;
3. JB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jimmy Breedlove

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09 Sep 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jimmy Breedlove

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09 Sept 2025

Date

Please have this section completed in the presence of a Notary Public.

State of MS, ss. County of Desoto

I, Jimmy Breedlove, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

09 Sept 2025

Date

Subscribed and Sworn to before me this 09 day of Sept.

Angela Cook

Notary Public Signature

STATE OF MISSISSIPPI
ANGELA RENA COOK
NOTARY PUBLIC
De Soto County
Commission Expires
August 31, 2026
COMMISSION NUMBER 126136

(Seal)

List of Teleflex LLC employees

Legal First Name	Legal Last Name	Position Title
Gary	Thomas	Distribution Center Supervisor
Mack	Harris	Quality Specialist III
Henry	Hoang	Senior Team Lead
Leroy	Cryer	Forklift Operator
Tamekia	Watkins	Learning & Development Coordinator
Dean	Frazier	Quality Technician I
James	Hensley	Facilities Manager
William	Stanback	Distribution Yard Hostler
Vandasia	Bryant	Distribution Process Analyst
William	McCall	Senior Distribution Center Manager
Derrick	Bradley	Team Lead
Glenda	Settle	Wave Planner
Tasha	Hall	International Production Control Supervisor
Wade	Jackson	Team Lead
Velda	Currie	Buyer
Latosha	Harper	Quality Specialist
Christopher	Katchens	Team Lead
Tamela	Jones	Transportation Coordinator
Ngoc Van	Vo	Distribution Associate I
Cassandra	Jackson	Wave Planner
Daniel	Darby	Production Control Supervisor
Montina	Hughes	Distribution Associate I
Tracy	Barnes	Wave Planner
Derrick	Granderson	Senior Team Lead
Derly	Ayala	SAP Super User
Kenisha	Shelton	Distribution Process Analyst
Hang	Le	Distribution Associate II
Sheree	DODSON ELLIOTT	Distribution Associate II
Della	Kimbrough	Distribution Associate I
Brian	Tolentino	Team Lead
Lorena	Lopez	Quality Technician I
Alice	Crutcher	Senior Team Lead
Jimmy	Breedlove	Receiving Manager, NADC
Mohamedou	Gadio	Senior Team Lead
Erica	Kilpatrick	Quality Technician I
Shaun	Berryhill	Distribution Center Supervisor
Sharon	Brantley	Distribution Associate I
Bobby	Bolton	Forklift Operator
Ruth	Wainaina	Distribution Center Coordinator - Inventory
Zuher	Beikhan	Forklift Operator
Ashley	Burgess	Distribution Associate II
Gatt	Williams	Forklift Operator
Doneese	Williams	Forklift Operator

List of Teleflex LLC employees

Jennifer	Wilson	Quality Technician I
Paul	Satcher	Forklift Operator
Christina	Fitz	Quality Technician III
Tangie	Sykes	Team Lead
Kendrick	Oliver	Forklift Operator
Candace	Mallory	Distribution Associate II
Sheila	Campbell	Distribution Associate I
John	Hankins	Forklift Operator
Lizet	Loya Soto	Desktop Support Administrator
Sandra Alicia	Magallanes Funes	Assistant Financial Controller
Audrey	Evans	International Coordinator
Patricia	Moses	Distribution Associate I
Savy	Duch	Distribution Associate I
Joyce	Vera	Distribution Associate II
Carlos	Vera	Team Lead
Tyler	Dicarlo	Distribution Center Supervisor
Donna	Rollins	Distribution Center Supervisor
Canesha	Luellen	Team Lead
John	Sullivan	Forklift Operator
Mauriceo	Walker	Flex Operations Supervisor
John	Lewis Jr.	Forklift Operator
Marco	Watson	Forklift Operator
Sharonda	Phillips-Glover	Distribution Associate II
Tina	Phillips	Distribution Associate I
Chauntay	Williams	Distribution Center Supervisor
Sharon	Jones	Team Lead
Chelsey	Rutherford	Distribution Associate II
Karl	DeBose	Distribution Center Supervisor
Michael	Wiggison	Team Lead
Marvin	Farmer	Forklift Operator
LiQuita	Phillips	Forklift Operator
James	Pike	Senior Team Lead
Marcus	Reed	Forklift Operator
Robert	Scott Jr.	Distribution Associate I
Jeffrey	Hayes	Senior Transportation Professional
Larrisha	Bell	Senior Team Lead
James	Brown	Forklift Operator
Angela	Cook	Transportation Coordinator
David	Hill	Distribution Center Manager
Daniel	Willman	Distribution Process Analyst II
Darlene	Regan	Controller, Americas L&D
Rauricas	Tate	Distribution Yard Hostler
Janice	Eldridge	Distribution Associate II
Coshia	Smith	Forklift Operator
Michael	Greene	Forklift Operator

List of Teleflex LLC employees

Issouf	Toure	Forklift Operator
Kevin	Malone	Forklift Operator
Carol	Williams	Project Manager, L&D Products & Services - Americas
Alvin	Cross	Forklift Operator
Kelvin	Nutall	Senior Business Intelligence Software Developer
Miquanius	Williams	Forklift Operator
Marian	Smith	Distribution Associate I
Robert	Pearson	Team Lead
Heriberto	Trinidad Cruz	Team Lead
Necole	Levy	Forklift Operator
Kristina	Miller	Senior Quality Excellence & Training Specialist
Noah	Waalk	Facilities Supervisor
Rachel	Rousseau	Human Resources Senior Manager
Ricardo	Gant	Distribution Center Supervisor
Shandrea	Hurns	Human Resources Generalist II
Robert	Bell	Forklift Operator
Joselin	Letet	Team Lead
Terry	Boyle	Forklift Operator
Roosevelt	Walker	Forklift Operator
Veronica	James	Forklift Operator
Willie	Mack	Forklift Operator
Quinton	Jackson	Forklift Operator
Leticia	Perez Bernardino	Distribution Associate I
CaDandrice	Lynn	Distribution Associate I
Kim	Wright	Team Lead
Raymond	West	Forklift Operator
Deadrick	Boyd	Distribution Associate I
Marian	Thompson	Distribution Associate I
David	Martino	Distribution Center Supervisor
Alisha	Hurst	Team Lead
Candace	Love	Forklift Operator
Krystal	Felston	Team Lead
Mercedes	Fragoso	Quality Assurance Specialist
Tito	Lazo	Forklift Operator
Salvador	Campos Reyes	Forklift Operator
Enrique	Faz	Forklift Operator
Virginia	Campos	Forklift Operator
John	Milam	Forklift Operator
Sharon	Wood	Distribution Center Supervisor
Whitney	Young	Distribution Associate I
Mamadou	Sow	Forklift Operator
Kendrick	Hymon	Forklift Operator
Tyrod	Williams	Forklift Operator
Leticia	Esteva	Forklift Operator
Sandra	Dowdy	Distribution Process Analyst II

List of Teleflex LLC employees

Terrance	Bee	Forklift Operator
Ranae	Baker	Forklift Operator
Ezekiel	Mongeri	Wave Planner
Jason	Mcintosh	Team Lead
Yesica	Juarez	Recruiter
Andres	Jimenez	International Trade Compliance Specialist LatAm
Douglas	Grantham	Facilities Services Technician II
Kimberly	Arrington	Staff Accountant
Shyvell	Kelly	Distribution Associate I
Jeremy	Chinn	Senior Manager, Enterprise Excellence L&D
Kristi	Flowers	Distribution Center Supervisor
Shamim	Kasemire	Distribution Process Analyst
Lilia	Hernandez	Distribution Associate I
Jamila	Gipson	Distribution Associate II
Tabioas	Jackson	Distribution Associate I
James	Williams	Forklift Operator
Robert	Smith	Quality Technician I
Melody	Morrow	Logistics Specialist
Alan	Hardrick	Forklift Operator
Marcus	Sanders	Distribution Center Supervisor
Keesler	Edwards	Distribution Associate II
Brandon	Johnson	Forklift Operator
Lawrence	Dorsey	Forklift Operator
Kelvin	Gordon	Distribution Associate I
John	Coleman	Team Lead
John	Ray	Logistics & Distribution Director
Laquasha	Lee	Distribution Associate I
Pablo	Rodríguez	Distribution Associate II
Emilio	Pascual	Forklift Operator
Ernie	Dean	Forklift Operator
Johvante	Turner	Forklift Operator
Pearline	Grandberry	Distribution Associate I
Joseph	Gaspar	Forklift Operator
Tyrone	Thomas	Distribution Yard Hostler
Carmine Alberto	Casañas	Quality Assurance Manager
James	Yates	Junior Project Manager, DC Transformation
Dionne	Grantham	Distribution Associate I
Michael	Thomas	General Manager, Logistics and Distribution Operations
Deshun	Hamilton	Forklift Operator
Regina	Chalmers	Distribution Associate II
Alexus	Staples	Distribution Associate I
Christian	Rodriguez	Distribution Associate I
Anthony	Massey	Distribution Associate I
Tracy	Swearengen	Team Lead
Teresa	Crutcher	Distribution Associate I

List of Teleflex LLC employees

Stephen	Evans	Distribution Associate I
Roymiya	Kilpatrick	Distribution Associate II
Vanessa	Bell	Distribution Associate II
Sharon	Harris	Distribution Associate II
Walneisha	Austin	Team Lead
Devonta	Dortch	Forklift Operator
Lorenzo	McClinton	Forklift Operator
Robbie	McClinton	Distribution Associate II
Xitlaly	Perez	Distribution Associate II
Rose	Bee	Distribution Associate I
Moria	Dalton	Quality Supervisor
Kevon	Brooks	Forklift Operator
Jalen	Brooks	Forklift Operator
Eveling	Perez	Distribution Associate I
Jorge	Nevarez Barrera	Enterprise Excellence Engineer
Demetrick	Ward	Forklift Operator
Jahmiya	Jackson	Distribution Associate I
Bryan	Redd	Forklift Operator
Gerald	Boykin	Forklift Operator
Fernando	Rodriguez	Environmental Health & Safety Manager
Maisha	Campbell	Team Lead
Patrick	Renfroe	Forklift Operator
Zedrian	Jones	Forklift Operator
Damon	Granderson	Forklift Operator
Cyrille	Roethlisberger	Transportation Manager - Americas
Viviana	Miranda	Forklift Operator
John	Hughbanks	Senior Manager, Distribution Center Strategy & Transformation
Randall	Thomas	Distribution Center Supervisor - Inventory Control
Jasmine	Jackson	Distribution Associate I
Stanley	Ayers	Forklift Operator
Jessica	Foster	Quality Specialist I
Bryan	Hubbard	Distribution Associate I
Shari	Carver	Distribution Associate II
Gina	Shields	Distribution Associate II
Gatt	Johnson	Forklift Operator
Mary	Jones	Distribution Associate I
Xiao	Sun	Project Engineer, DC Processes & Systems Transformation
Nathan	Thomas	Forklift Operator
Nathaniel	Bullard	Forklift Operator
Zaquan	Phillips	Forklift Operator
Kevius	Malone	Forklift Operator
Jerrica	Taylor	Distribution Associate I
Brianna	Jefferys	Forklift Operator
Nicholas	McDaniel	Facilities Services Technician III
Kimyotta	Fernanders	Senior Logistics & Distribution Quality Manager Americas

List of Teleflex LLC employees

Brian	Savage	Forklift Operator
Matthew	Pulley	Facilities Services Technician I
Yolanda	Zuniga	Distribution Associate I
Abdel	Marrero Rodriguez	Forklift Operator
Elijah	Torres	Forklift Operator
Angela	Jackson	Distribution Associate II
Daniel	Juarez	Forklift Operator
Ricardo	Amezquita	Intercompany Buyer/Planner
Christina	Bowman	Quality Technician I
India	Cole	Distribution Associate I
Kyrah	Lovett	Quality Specialist II
Deivi	Perez Gonzalez	Forklift Operator
Shani	Knox	Forklift Operator
Ronald	Malone	Forklift Operator
David	Martinez	Forklift Operator
Marvin	Quarles	Forklift Operator
Christian	Rodriguez	Forklift Operator
Ronald	Greer	Forklift Operator
Marlon	Smaw	Distribution Associate I
Tanisha	Harper	Distribution Associate I
LaShonda	Richardson	Team Lead
Toni	Anders	Forklift Operator
Alexis	Boyce	Forklift Operator
Ezell	Neal	Forklift Operator
Shakeya	Moore	Distribution Associate I
Ema	Martinez	Distribution Associate I
Amber	Smith	Distribution Associate I
Amauri	Marbly	Forklift Operator
Toni	Coffer	Distribution Associate I
Ameannia	Smith	Forklift Operator
Tarsha	Bell	Distribution Associate I
Toinetta	Peterson	Distribution Associate I
Tyrone	Randle	Forklift Operator
Carrie	Alice	Distribution Associate II
Eduardo	Sosa	Supplier Quality Engineer II
Dajah	Harris	Forklift Operator
Melanie	Hill	Forklift Operator
Jarvise	Jones	Forklift Operator
Megal	Holliday	Forklift Operator
Jacqueline	Perez	Distribution Associate I
Alexia	Evans	Distribution Associate I
Yolanda	Holmes	Team Lead
Deterrio	Guy	Forklift Operator
Christian	Martinez	Forklift Operator
Elecia	Brown	Distribution Associate II

List of Teleflex LLC employees

Dawson	Bunn	Distribution Associate II
Mouhamadou	Ndiaye	Forklift Operator
Allen	Claiborne	Forklift Operator
Antmari	Gil	Distribution Associate I
Dallas	Mcgrew	Forklift Operator
Toya	Barber	Distribution Associate I
Cassaundra	Palmore	Forklift Operator
Dominic	Musarra	Distribution Associate I
Mamoudou	Basse	Distribution Associate I
Dorayci	Valero	Distribution Associate II
Hericson	Padron	Forklift Operator
Yohelvis	Pérez	Forklift Operator
Abdoulaye	Kane	Forklift Operator
Teddrick	Boyd	Forklift Operator
Levitta	Coleman	Quality Engineer, Distribution
Rodrecous	Hamilton	Distribution Center Supervisor
Amanda	Polanco	Distribution Associate I
Jada	Banks	Distribution Associate I
Antonio	Stewart	Distribution Associate I
Cristian	Morales Salvat	Distribution Associate I
Brandon	Shotwell	Forklift Operator
Ena	Garcia	Distribution Associate I
Derrick	Bradley	Forklift Operator
Jameka	Williams	Forklift Operator
Keith	Hightower	Forklift Operator
Sabrina	Gotera	Distribution Associate II
Jesus	Rondon	Forklift Operator
Ashiya	Brown	Distribution Associate II
Macarya	Smith	Distribution Associate II
Jalen	Philmore	Forklift Operator
Henry	Ellis	Forklift Operator
Corzerrius	Calhoun	Forklift Operator
Ivette	Carmona	Distribution Associate II
Melvin	Austin	Quality Engineer Supervisor
Sarah	Pira	Distribution Associate I
Nadia	Sanchez	Distribution Associate I
Ruben	Maquinales	Forklift Operator
Ruben	Lopez	Distribution Associate I
Erick	Pirela	Forklift Operator
DeAngelo	Leggett	Distribution Associate I
Renee	Safir	Forklift Operator
Leobardo	Lopez	Distribution Associate I
Luis	Ramos	Forklift Operator
Cierra	Simmons	Forklift Operator
Jasmine	Birchfield	Team Lead

List of Teleflex LLC employees

Robert	Jones	Forklift Operator
Antonio	Primera	Forklift Operator
Luis	Carreno Leon	Forklift Operator
Kelsey	Wilkerson	Distribution Associate I
Rashardo	Shields	Forklift Operator
Haleigh	Staff	Distribution Associate II
Marcus	Merriweather	Forklift Operator
Yoleyda	Garcia	Distribution Associate I
Gloria	Barrientos	Distribution Associate I
Michael	Reisedge	Distribution Associate I
Austen	Reeves	Distribution Associate I
Darrell	Kinney	Forklift Operator
Nicolas	Nelums	Forklift Operator
Lizz	Montes	Distribution Associate I
Rebecca	De leon	Distribution Associate I
Kendra	Kilpatrick	Forklift Operator
Lanikya	Harris	Forklift Operator
Ezekial	Coleman isom	Forklift Operator
Jacob	Williams	Distribution Associate I
Demarcus	Ware	Forklift Operator
John	Burnside	Distribution Associate I
Janet	Roaf	Distribution Associate I
Chad	Erwin	Forklift Operator
Chelsea	Grant	Distribution Associate I
Idrissa	Kane	Distribution Associate I
Marcus	Strong	Forklift Operator
Jakevia	Stamps	Forklift Operator
Holli	Erwin	Distribution Associate I
Nastasia	Hunt	Forklift Operator
Preston	Rice	Facilities Intern
Berhoney	Wiggins	Distribution Associate I
Dequavion	Lewis	Distribution Associate I
Angelina	Jones	Distribution Associate I
Sharnesia	Quinn	Distribution Associate I
Tascha	Rhodes	Forklift Operator
Chauncey	Seldon	Team Lead
Carl	Duesterbeck	Team Lead
Jill	McGaugh	Forklift Operator
Ukeela	Brown	Quality Technician I
Elizabeth	Zepponi	Distribution Associate I
Austran	Jefferson	Distribution Associate I
Claudia	Carreno	Distribution Associate I
Brittney	Seldon	Distribution Associate I
Tia	Johnson	Associate Quality Engineer
Logan	Cowart	Material Handler

List of Teleflex LLC employees

Joel	Lecaro	Team Lead
Kyra	Morrison	Distribution Associate I
Harold	Rigsby	Forklift Operator
Freddy	Uzcategui	Forklift Operator
Alejandra	Gotera	Distribution Associate II
Emily	Ferrell	Distribution Associate I
Maria	Parra	Distribution Associate I
Kevin	Espinoza	Distribution Associate I
Christopher	Victoria	Forklift Operator
Edixon	Gil	Forklift Operator
Aiden	Sloan	Distribution Associate I
Tiffany	Wilson	Distribution Associate I
Timothy	Goliday	Distribution Associate I
Francisco	Jiménez	Distribution Associate I
Keirra	Johnson	Forklift Operator
Brandon	Hardaway	Distribution Associate I
Ernesto	Murray	SAP Warehouse & Distribution Analyst

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Abrasive Technology, LLC

Physical Address: 8400 Green Meadows Drive North

City: Lewis Center State: OH Zip: 43035

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 740-548-4100 Website: www.abrasive-tech.com

Name of Designated Representative (DR): Shelly Zbiegien Kipp

Licensing Company Email: compliance.abrasivetech@gmail.com DR Email: skipp@abrasive-tech.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Dentists, Dental Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Abrasive Technology Acquisition, LLC

Corporation/Organization Name: Abrasive Technology, LLC

Mailing Address: 8400 Green Meadows Drive North

City: Lewis Center State: OH Zip: 43035

Telephone: 740-548-4100 Email: compliance.abrasivetech@gmail.com

Contact Person Name: Shelly Zbiegien Kipp

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Shuz Kipps
Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Abrasive Technology, LLC

Facility Name

Shelly Zbiegien Kipp

Print Name of Authorized Person Submitting Application

Shelly Zbiegien Kipp

Original signature of Authorized Person (copies or stamps not accepted)

12-01-25

Date

Board Use Only	Date Received: 12/15/25	Amount: $1000-Ck 2236

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: Labeler code - HIBC LIC- B868 http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
ABRASIVE TECHNOLOGY, LLC
8400 Green Meadows Drive N.
LEWIS CENTER, OH 43035
Registration Number: 1525838
FEI Number*: 1525838
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
ABRASIVE TECHNOLOGY, LLC[6]
8400 Green Meadows Drive N.
Lewis Center, OH US 43035
Owner/Operator Number: 1525838[7]

Official Correspondent:
Shelly Z Kipp
Abrasive Technology LLC
8400 Green Meadows Drive North
Lewis Center, OH 43035
Phone: 01-740-5484100-2268

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1525838&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryNa
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1525838&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryNa

Page Last Updated: 12/15/2025

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

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FDA

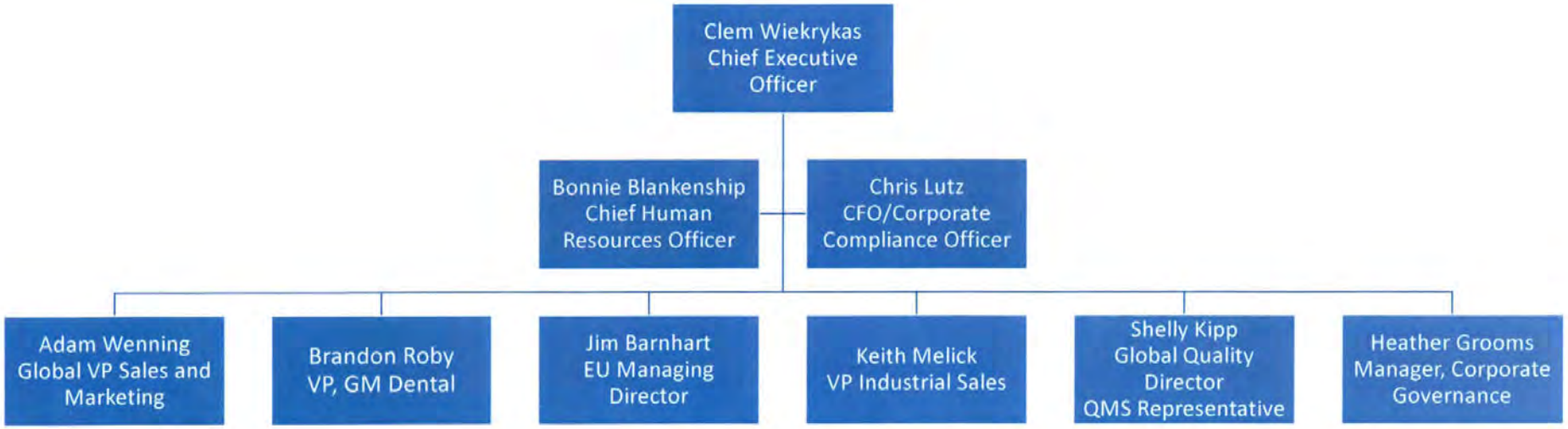
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

FDA Registration

ABRASIVE TECHNOLOGY, LLC
8400 Green Meadows Drive N.
LEWIS CENTER, OH 43035
Registration Number: 1525838
FEI Number*: 1525838
Status: Active
Initial Distributor/Importer: Yes

Senior Leadership



abrasive technology

Abrasive Technology LLC Officer List

List of Current Officers:

Full Name: Clement David Wiekrykas
Title/Position: Chief Executive Officer, President, Treasurer and Secretary
Phone Number: [redacted]
Home Address: [redacted]
Email Address: cwiekrykas@abrasive-tech.com

abrasive technology

Abrasive Technology LLC

Officers List

Full Name: Clement David Wiekrykas
Title/Position: Chief Executive Officer, President, Treasurer and Secretary
Date of Birth: [redacted]
Business address: 8400 Green Meadows Drive North, Lewis Center, OH 43035

OWNERSHIP
Abrasive Technology Acquisition, LLC is 100% owner of the Abrasive Technology LLC
Address: 8400 Green Meadows Dr, Lewis Center, OH 43035

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ABRASIVE TECHNOLOGY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF DECEMBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5879777 8300

SR# 20254803979

Authentication: 205550626

Date: 12-09-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

eLicense Ohio
Professional Licensure

License Look Up

12/30/2025 4:12 PM

Abrasive Technology, LLC

License Number	0150000101
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Manufacturer - Category 2
License Issue Date	1/29/24
License Expiration Date	6/30/27
License Effective Date	7/1/25
Street Address	8400 Green Meadows Dr N
City	Lewis Center
State	OH
Zipcode	43035-9453
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
		Active	Tue Sep 19 00:00:00 GMT 2023	

Current date & time: **12/30/2025 4:12 PM**

0766

Client#: 1988031 ABRASTEC

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 1/06/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer any rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Donna L Dooley
USI Insurance Services LLC 2001 Spring Road, Ste 200 Oak Brook, IL 60523 312 442-7200	PHONE (A/C, No, Ext): 312 442-7200 FAX (A/C, No): 610 362-8900 E-MAIL ADDRESS: donna.dooley@usi.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Travelers Property Cas. Co. of America	25674
INSURER B : Travelers Indemnity Co of America	25666
INSURER C : Phoenix Insurance Company	25623
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Abrasive Technology Ultimate Holdings,
8400 Green Meadows Dr N
Lewis Center, OH 43035-9453

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			6309T691057	01/01/2026	01/01/2027	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$300,000
							MED EXP (Any one person)	$10,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$1,000,000
	POLICY PRO-JECT LOC						GENERAL AGGREGATE	$2,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$2,000,000
								$
C	AUTOMOBILE LIABILITY			BA9T6905092514G	01/01/2026	01/01/2027	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			UB9T693002	01/01/2026	01/01/2027	X PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$1,000,000
							E.L. DISEASE - POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
This Certificate is issued for insureds normal business operations.

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Thomas W Chisholm

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AHGZP 0767

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. CIC1959835

Application/License No. _____

Abrasive Technology, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8400 Green Meadows Dr, Lewis Center, OH 43035-9453 (Address of Applicant/Principal), as PRINCIPAL, and Capitol Indemnity Corporation (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is P.O. Box 5900, Madison, WI 53705 - 0900 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 11/04/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of November, 2025.

APPLICANT/PRINCIPAL

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Surety Company's Representative

Liz Talbott, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Meghan Schraer

Witness Kathrine Krekeler

Countersigned by:

Nevada NonResident Agent Tiffiany Gobich

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, That the **CAPITOL INDEMNITY CORPORATION**, a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

----------RANDAL NOAH; LIZ TALBOTT; NANCY NEMEC; TAMMY L. MASTERSON; TIFFIANY GOBICH; KELSEY BECKER ----------
----------AUDRIA COLEMAN; KATHRINE KREKELER; MARK NELSON; MEGHAN SCHRAER; TRINITY LUKENS; GLADYS D. ROGERS --------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

---------- ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED: $20,000,000.00 ----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **CAPITOL INDEMNITY CORPORATION** at a meeting duly called and held on the 15th day of May, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **CAPITOL INDEMNITY CORPORATION** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of September, 2022.

Attest:

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Todd Burrick
Chief Underwriting Officer

CAPITOL INDEMNITY CORPORATION CORPORATE SEAL WISCONSIN

CAPITOL INDEMNITY CORPORATION

Adam L. Sills
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

On the 1st day of September, 2022 before me personally came Adam L. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is Chief Executive Officer and President of **CAPITOL INDEMNITY CORPORATION**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE NOTARY PUBLIC STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in **CAPITOL INDEMNITY CORPORATION**, a Wisconsin Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 4th day of November, 20 25.

CAPITOL INDEMNITY CORPORATION CORPORATE SEAL WISCONSIN

Suzanne M. Broadbent
Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Abrasive Technology, LLC — MDEG License # (if applicable): N/A

Physical Address: 8400 Green Meadows Drive North

City: Lewis Center — State: OH — Zip: 43035

Mailing Address (if different from physical address): Same as above

City: — State: — Zip:

Telephone: 740-548-4100 — Website: www.abrasive-tech.com

Licensing Company Email: compliance.abrasivetech@gmail.com

Section 2: Personal Information

First: Shelly — Middle: Zbiegien — Last: Kipp

Alias(es, nicknames, name changes, etc.): Shelly Zbiegien

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: 8400 Green Meadows Drive North

City: Lewis Center — State: OH — Zip: 43035

Telephone: [redacted] — Email: compliance.abrasivetech@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Warner University		02/05-08/11	
Address	**City**	**State**	**Zip**
13895 US Hwy 27	Lake Wales	FL	33859
Diploma/Degree obtained, if any			
BA in Organizational Management			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/13-03/19	[redacted]	Fredericktown	OH	[redacted]
03/19-03/24		Marion	OH	
03/24-Present		Lewis Center	OH	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Abrasive Technology, LLC			05/23 - PRESENT
Business Address	**City**	**State**	**Zip**
8400 Green Meadows Drive North	Lewis Center	OH	43035
Phone	**Title**	**Number of Employed Hours**	
740-548-4100	Director Quality Assurance/Regulatory Compliance	3,640	

Description of Duties

Providing leadership to the Quality Assurance team, developing quality processes and procedures. Overseeing medical device regulatory compliance, import/export process, aerospace process, internal/eternal audit programs, and industrial inspection process.

Business Name			From - To (MM/YY – MM/YY)
Bertec Corporation			03/19 - PRESENT
Business Address	**City**	**State**	**Zip**
2500 Citygate Dr	Columbus	OH	43219
Phone	**Title**	**Number of Employed Hours**	
(614) 543-1127	Quality Assurance/Regulatory Compliance Manager		

Description of Duties

Overseeing daily operations, managing staff, ensuring compliance with medical device registrations, both domestic and worldwide. Responsible for analyzing trends in quality and providing detail to executive leadership. Worked with Director of Regulatory Compliance to ensure compliance to MDD/MDR and FDA regulations.

Business Name			From - To (MM/YY – MM/YY)
Abrasive Technology Inc.			08/11 - 03/19
Business Address	**City**	**State**	**Zip**
8400 Green Meadows Drive North	Lewis Center	OH	43035
Phone	**Title**	**Number of Employed Hours**	
740-548-4100	Quality Assurance		

Description of Duties

Responsible for Aerospace internal/external audit program, Nadcap audit compliance, medical device audits (internal, MDD & MDSAP).

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Shelly Kipp

Original Signature (electronic, copies or stamps not accepted)

12-2-25

Date

I, Shelly Zbiegien Kipp, **certify that as the MDEG Administrator for**

Abrasive Technology, LLC,

that I (initial that you have read and meet the following requirements):

1. SK Have a high school diploma or its equivalent;
2. SK Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SK Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SK Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shelly Kipp
Print Name (First, Last)

Shelly Kipp
Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

Board Use Only	Date Received: 12/15/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Abrasive Technology, LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 8400 Green Meadows Drive North

City: Lewis Center State: OH Zip: 43035

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 740-548-4100 Website: www.abrasive-tech.com

Licensing Company Email: compliance.abrasivetech@gmail.com

Section 2: Personal Information

First: Shelly Middle: Zbiegien Last: Kipp

Alias(es, nicknames, name changes, etc.): Shelly Zbiegien

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☐ M ☒ F ☐ X

Mailing Address: 8400 Green Meadows Drive North

City: Lewis Center State: OH Zip: 43035

Telephone[redacted] Email: compliance.abrasivetech@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Warner University		02/05-08/11	
Address	**City**	**State**	**Zip**
13895 US Hwy 27	Lake Wales	FL	33859
Diploma/Degree obtained, if any			
BA in Organizational Management			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/13-03/19	[redacted]	Fredericktown	OH	[redacted]
03/19-03/24		Marion	OH	
03/24-Present		Lewis Center	OH	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Abrasive Technology, LLC			05/23 - PRESENT	
Business Address		City	State	Zip
8400 Green Meadows Drive North		Lewis Center	OH	43035
Phone	Title		Number of Employed Hours	
740-548-4100	Director Quality Assurance/Regulatory Compliance		3,640	
Description of Duties				
Providing leadership to the Quality Assurance team, developing quality processes and procedures. Overseeing medical device regulatory compliance, import/export process, aerospace process, internal/eternal audit programs, and industrial inspection process.				

Business Name			From - To (MM/YY – MM/YY)	
Bertec Corporation			03/19 - PRESENT	
Business Address		City	State	Zip
2500 Citygate Dr		Columbus	OH	43219
Phone	Title		Number of Employed Hours	
(614) 543-1127	Quality Assurance/Regulatory Compliance Manager			
Description of Duties				
Overseeing daily operations, managing staff, ensuring compliance with medical device registrations, both domestic and worldwide. Responsible for analyzing trends in quality and providing detail to executive leadership. Worked with Director of Regulatory Compliance to ensure compliance to MDD/MDR and FDA regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Abrasive Technology Inc.			08/11 - 03/19	
Business Address		City	State	Zip
8400 Green Meadows Drive North		Lewis Center	OH	43035
Phone	Title		Number of Employed Hours	
740-548-4100	Quality Assurance			
Description of Duties				
Responsible for Aerospace internal/external audit program, Nadcap audit compliance, medical device audits (internal, MDD & MDSAP).				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Shelly Kipp
Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

I, Shelly Zbiegien Kipp, **certify that as the designated representative for**

Abrasive Technology, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SK I am at least 21 years of age;
3. SK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Shelly Kipp

Print Name (First, Last)

Shelly Kipp

Original Signature (electronic, copies or stamps not accepted)

12-2-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shelly Kipp

Print Name (First, Last)

Shelly Kipp — 12-2-25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Delaware

I, Shelly Kipp, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Shelly Kipp — 12-2-25

Original Signature — **Date**

Subscribed and Sworn to before me this 2 day of December.

Heather Grooms

Notary Public Signature

Heather Grooms
Notary Public, State of Ohio
My Commission Expires 10-25-2026

(Seal)

Employee Organization Chart Medical Manufacturing

Philip Patterson - Leadership
Melinda Bortz – Leadership
Muoi Ly-ta – Operations
Nu Ly – Operations
Robin Reed – Operations
Tonya Main – Operations
Cuong Ta – Operations
Pamela Semer – Operations
Tiffanie Donohoe – Packaging
Irma Julio – Operations
Judy Stoddard – Finishing
Koziar Jacobs – Operations
Crystal Wood – Packaging
Billy Joyce – Finishing
Jeremy Johnson – Operations
Dillon West - Operations
Rebecca Ho – Finishing
Rosa Slivka – Operations
Minu Tuladhar – Finishing
Aurthur Weaver – Operations
Deborah Steward – Operations
Tessa Meadows – Operations
Denise Jordan-Cooper – Operations
Destiny Robinson – Operations
Yolaisi Rojas – Finishing
Wendy Ramirez – Operations
William Potter – Operations
Olivia Jackson – Operations
Lance Ross – Operations
Patricia Crawley – Operations
Jason Monsul – Quality Engineering
Walter Hanson - Engineering

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Aiping Pharmaceutical, Inc.

Physical Address: 350 Wireless Blvd

City: Hauppauge State: NY Zip: 11788

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 631-465-4089 Website: www.aipingpharma.com

Name of Designated Representative (DR): Ajay Vemula

Licensing Company Email: compliance.aipingpharma@gmail.com DR Email: compliance.aipingpharma@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: OTC Drugs	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

12/10/2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: A&Z Pharmaceutical, Inc
Address: 180 Oser Avenue City: Hauppauge State: NY Zip: 11788

Name: Cardinal Health 105 LLC dba Specialty Pharmaceutical Services
Address: 501 Mason Road City: La Vergne State: TN Zip: 37086

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NY
Parent Company (if any):
Corporation/Organization Name: Aiping Pharmaceutical, Inc.
Mailing Address: 350 Wireless Blvd
City: Hauppauge State: NY Zip: 11788
Telephone: 631-465-4089 Email: avemula@aipingpharma.com
Contact Person Name: Ajay Vemula

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: Labeler Code 11788 http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf. Attached.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Aiping Pharmaceutical, Inc.

Facility Name

Ajay Vemula

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/10/2025

Date

Board Use Only	Date Received: 12/23/25	Amount: $1000-CK 2270

/ NDC (index.cfm)

National Drug Code Directory

Current through December 18, 2025

You have searched Finished drug products

Search Results: *'11788'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Amitriptyline Hydrochloride	11788-077-01	10 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-077	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-077-01)
Amitriptyline Hydrochloride	11788-077-10	10 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-077	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	1000 TABLET in 1 BOTTLE (11788-077-10)
Amitriptyline Hydrochloride	11788-078-01	25 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-078	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-078-01)
Amitriptyline Hydrochloride	11788-078-10	25 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-078	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	1000 TABLET in 1 BOTTLE (11788-078-10)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Amitriptyline Hydrochloride	11788-079-01	50 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-079	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-079-01)
Amitriptyline Hydrochloride	11788-079-10	50 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-079	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	1000 TABLET in 1 BOTTLE (11788-079-10)
Amitriptyline Hydrochloride	11788-080-01	75 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-080	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-080-01)
Amitriptyline Hydrochloride	11788-081-01	100 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-081	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-081-01)
Amitriptyline Hydrochloride	11788-082-01	150 mg/1	TABLET	ORAL	ANDA212654	AiPing Pharmaceutical, Inc.	11788-082	Amitriptyline Hydrochloride	AMITRIPTYLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-082-01)
Buspirone hydrochloride	11788-057-01	5 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-057	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-057-01)
Buspirone hydrochloride	11788-057-05	5 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-057	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	500 TABLET in 1 BOTTLE (11788-057-05)
Buspirone hydrochloride	11788-058-01	7.5 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-058	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-058-01)
Buspirone hydrochloride	11788-059-01	10 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-059	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-059-01)
Buspirone hydrochloride	11788-059-05	10 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-059	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	500 TABLET in 1 BOTTLE (11788-059-05)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Buspirone hydrochloride	11788-060-01	15 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-060	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-060-01)
Buspirone hydrochloride	11788-060-05	15 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-060	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	500 TABLET in 1 BOTTLE (11788-060-05)
Buspirone hydrochloride	11788-061-05	30 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-061	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	500 TABLET in 1 BOTTLE (11788-061-05)
Buspirone hydrochloride	11788-061-60	30 mg/1	TABLET	ORAL	ANDA202087	AiPing Pharmaceutical, Inc.	11788-061	Buspirone hydrochloride	BUSPIRONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/26/2025	N/A	ANDA	60 TABLET in 1 BOTTLE (11788-061-60)
D-Cal Kids	11788-021-03	750 mg/1	TABLET, CHEWABLE	ORAL	part331	AiPing Pharmaceutical, Inc.	11788-021	Calcium Carbonate	CALCIUM CARBONATE	HUMAN OTC DRUG	09/17/1997	N/A	OTC MONOGRAPH DRUG	30 TABLET, CHEWABLE in 1 BOTTLE (11788-021-03)
MELOXICAM	11788-098-00	7.5 mg/1	TABLET	ORAL	ANDA077920	AiPing Pharmaceutical, Inc.	11788-098	Meloxicam	MELOXICAM	HUMAN PRESCRIPTION DRUG	05/02/2024	N/A	ANDA	83000 TABLET in 1 CARTON (11788-098-00)
MELOXICAM	11788-099-00	15 mg/1	TABLET	ORAL	ANDA077920	AiPing Pharmaceutical, Inc.	11788-099	Meloxicam	MELOXICAM	HUMAN PRESCRIPTION DRUG	05/02/2024	N/A	ANDA	83000 TABLET in 1 CARTON (11788-099-00)
SEVELAMER CARBONATE	11788-116-07	800 mg/1	TABLET	ORAL	ANDA215998	AiPing Pharmaceutical, Inc.	11788-116	SEVELAMER CARBONATE	SEVELAMER CARBONATE	HUMAN PRESCRIPTION DRUG	12/15/2025	N/A	ANDA	270 TABLET in 1 BOTTLE (11788-116-07)
SOTALOL HYDROCHLORIDE	11788-051-01	80 mg/1	TABLET	ORAL	ANDA075500	AiPing Pharmaceutical, Inc.	11788-051	SOTALOL HYDROCHLORIDE	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-051-01)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
SOTALOL HYDROCHLORIDE	11788-052-01	120 mg/1	TABLET	ORAL	ANDA075500	AiPing Pharmaceutical, Inc.	11788-052	SOTALOL HYDROCHLORIDE	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-052-01)
SOTALOL HYDROCHLORIDE	11788-053-01	160 mg/1	TABLET	ORAL	ANDA075500	AiPing Pharmaceutical, Inc.	11788-053	SOTALOL HYDROCHLORIDE	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-053-01)
SOTALOL HYDROCHLORIDE	11788-054-01	240 mg/1	TABLET	ORAL	ANDA075500	AiPing Pharmaceutical, Inc.	11788-054	SOTALOL HYDROCHLORIDE	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/01/2025	N/A	ANDA	100 TABLET in 1 BOTTLE (11788-054-01)

Showing 1 to 26 of 26 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

AIPING PHARMACEUTICALS, INC

Name	% of ownership	Title/position	Address	Phone Number
Emma Li Xu	100%	CEO	[redacted]	
Ajay Vemula	0%	COO		

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	AIPING PHARMACEUTICAL, INC.
DOS ID Number:	4569592
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	04/30/2014
Statement Status:	CURRENT
Statement Due Date:	04/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on March 14, 2025 at 02:05 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100007656580 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-25

NAME OF SUPERVISOR
AJAY VEMULA

THIS IS TO CERTIFY

AIPING PHARMACEUTICAL, INC.
350W WIRELESS BLVD.
HAUPPAUGE, NY 11788

is duly recorded as a

REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF JANUARY, 2023.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF DECEMBER, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
035100

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. TIC059109

Application/License No. _____

AiPing Pharmaceutical, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 350 Wireless Blvd., Hauppauge, NY 11788 (Address of Applicant/Principal), as PRINCIPAL, and Trisura Insurance Company (Surety Company), a corporation organized under the laws of the state of Oklahoma (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2 Stamford Plaza, Suite 1504, 281 Tresser Blvd, Stamford, CT 06901 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on December 4, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of December, 2025.

APPLICANT/PRINCIPAL
AiPing Pharmaceutical, Inc.

Authorized Representative

SURETY COMPANY
Trisura Insurance Company

Surety Company's Representative

Robyn Rost, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Karla Luongo

Witness Julia Quelly

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

2 Stamford Plaza
Suite 1504, 281 Tresser Boulevard
Stamford, Connecticut 06901
us.surety@trisura.com

POWER OF ATTORNEY

Bond Number: TIC059109
Bond issuance date: December 4, 2025

KNOW ALL MEN BY THESE PRESENTS: That **TRISURA INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Oklahoma, authorized to conduct a surety business, and having its principal place of business at 2 Stamford Plaza, Suite 1504, Tresser Boulevard, Stamford, Connecticut 06901, does hereby constitute and appoint:

Robyn Rost, Pamela Beth Lipkin-Sauertig

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **TRISURA INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **TRISURA INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **TRISURA INSURANCE COMPANY** at a meeting duly held on the **11th** day of **December, 2020.**

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **TRISURA INSURANCE COMPANY** have each executed and attested these presents

on this 25th day of February, 2022.

STATE OF Connecticut
County of Fairfield

George Jamos, Chief Underwriting Officer, Surety

Trisura Insurance Company CORPORATE SEAL

On this **25th** day of **February, 2022**, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **TRISURA INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at Fairfield, Connecticut the day and year first above written.

SERENA I. SZEKELY
Notary Public, State of Connecticut
My Commission Expires 10/31/2026

Serena I Szekely seal

, a Notary Public of Connecticut

My Commission Expires: **10/31/2026**

CERTIFICATION

I, the undersigned officer of **TRISURA INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, December 4, 2025

Richard Grant

Richard Grant, Vice President, U.S. Surety

TO CONFIRM AUTHENTICITY OF THIS BOND OR DOCUMENT EMAIL: us.surety@trisura.com

TRISURA INSURANCE COMPANY

STATUTORY-BASIS STATEMENTS OF ADMITTED ASSETS,LIABILITIES, AND CAPITAL SURPLUS

AS OF DECEMBER 31, 2024

	2024
Admitted Asstes	
Bonds	$ 104,937,419
Preferred Stocks	1,214,087
Common Stocks	168,951,106
Cash, cash equivalents and short-term investments	55,946,135
Receivable for securities	205,707
Total cash and invested assets	331,254,454
Uncollected premiums	130,848,319
Investment income due and accrued	1,251,739
Amounts recoverable from reinsurers	52,773,785
Net deferred Tax asset	8,839,874
Receivables from Parents and affiliates	5,645,396
Total admitted assets	$ 530,613,567
Liabilities	
Net losses and loss adjustement expenses	$ 30,612,957
Net unearned premium reserve	53,387,461
Ceded reinsurance premiums payable (net of ceding commissions)	133,382,400
Commissions payable, contingent commissions and other similar changes	17,353,815
Deferred commissions	6,860,154
Payable for paid losses	23,456,420
Current federal and foreign income taxes (including $... on realized capital gains (losses))	3,137,301
Net deferred tax liability	-
Other expenses payable	47,469,916
Funds held by company under reinsurance treaties	18,461,134
Payable to subsdiaries and affiliates	-
Provision for reinsurance	1,833,784
Total liabilities	335,955,342
Surplus as regards policyholders	
Common Stock,	4,200,000
Gross paid in contributed surplus	228,123,947
Unassigned surplus (deficit)	37,665,722
Total surplus as regards policyholders	194,658,225
Total liabilities & surplus as regards policyholders	$ 530,613,567

I, Allison M. Kenworthy, hereby certify that I am the Chief Financial Officer of Trisura Insurance Company, a corporation duly authorized under the laws of the State of Oklahoma, licensed and engaged in the State of Oklahoma, and duly qualified to act as Surety under such laws. I further certify that I am authorized to make this certification on its behalf, and that the foregoing is a fair statement of Admitted Assets, Liabilities and Capital and Surplus as of December 31,2024, as reflected by its books and records and as reported in its statement on file with Oklahoma Insurance Department.



Allison M. Kenworthy, CFO

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Aiping Pharmaceutical, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 350 Wireless Blvd

City: Hauppauge State: NY Zip: 11788

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 631-465-4089 Website: www.aipingpharma.com

Licensing Company Email: compliance.aipingpharma@gmail.com

Section 2: Personal Information

First: Ajay Middle: Last: Vemula

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 350 Wireless Blvd

City: Hauppauge State: NY Zip: 11788

Telephone: 631-465-4089 Email: avemula@aipingpharma.com

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Governors State University		2007-2008	
Address	**City**	**State**	**Zip**
1 University Parkway	University Park	IL	60484
Diploma/Degree obtained, if any			
Masters in Analytical Chemistry			

School Name		From - To (MM/YY – MM/YY)	
SRM College of Pharmacy		2004-2008	
Address	**City**	**State**	**Zip**
SRM Nagar Potheri, Kattankulahtur, India			
Diploma/Degree obtained, if any			
Bachelor Of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16 - Present	[redacted]	Smithtown	NY	[redacted]
03/12 - 08/16		Hauppauge	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Aiping Pharmaceutical, Inc.			09/17 - present	
Business Address		City	State	Zip
350 Wireless Blvd		Hauppauge	NY	11788
Phone	Title		Number of Employed Hours	
631-465-4089	COO		16,120+ Hours	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Ajay Vemula

[redacted]

Chief Operating Officer

Purpose-driven science and business leader; fosters collaborative innovation; range of current accountability encompasses all of the company's Quality Management Systems. Dedicated to creating strategic solutions that impact company growth and drive objectives. With proven success to identifying core issues and creating solutions that eliminate waste and build the foundation for success. Seeking to benefit a top-level organization by improving performance, influencing positive changes, and contributing to the world of Pharmaceuticals. ***Proven expertise in:***

- Leadership and Teambuilding
- Training and Development Programs
- Quality Operations Management
- Root Cause Identification
- Strategic Planning and Analysis
- 21 CFR Part 11 Compliance
- Corrective & Preventive Actions (CAPA)
- Quality Improvement initiatives
- Financial/Budget Administration
- Handling of Regulatory Inspections
- Analytical Development/QC Testing
- Pharmaceutical Industry Standards
- Computer Systems Validations for GMP environments

EDUCATION AND CERTIFICATION

Master's Degree in Analytical Chemistry GPA: 3.3
Governor's State University, University Park, IL

Bachelor's Degree in Pharmacy (B.Pharm) GPA: 3.5
SRM College of Pharmacy, Tamilnadu Dr. MGR Medical University, Chennai, India

Technical Skills

Analytical Software: Empower, Total Chrome, Chromeleon, Dionex, Lab Solutions, Tiamo, Chemdraw, Chemstation, Orbit (NMR), Omnic (IR); Office Software: MS Office, Adobe Photoshop, Excel

PROFESSIONAL EXPERIENCE

A&Z Pharmaceuticals

Director Of Quality Operations, Oct-2017 to Jan 2022

Vice President Of Operations, Jan 2022 to Jan 2023

Chief Operating Officer, Jan 2023 to Now

- Optimize effectiveness and efficiency of the quality function to ensure performance goals are achieved or exceeded without compromising quality and compliance.
- Lead, mentor and manage performance of Quality staff (QA & QC), including training, setting goals and objectives
- Provide oversight on day to day activities to ensure overall operational efficiency of the quality function
- Identify process, quality and GMP related gaps and provide appropriate resolution
- Approve protocols, investigation reports, SOPs, master batch records, master packaging records and other documents as necessary
- Analyze product quality complaints, stability studies, deviations and validation processes for all OTC and Rx products
- Ensure all open CAPA's, Investigations, Deviations are closed in a timely and effective manner.

...continued...

- Review technical documentation, also review the data for integrity
- Lead and engage in on-site FDA inspection and customer audits. Manage response to audit findings and submit the timely response
- Conduct bi-annual quality management system reviews to provide updates to the leadership team
- Ensure quality agreements are in place with all the GXP contractors, distributors and service providers
- Provide oversight to develop and maintain an effective system to handle market complaints
- Interface with third party manufacturers to ensure complaints on drug quality and product efficacy are reported as per the SOP
- Manage communication with customers, FDA representatives and operations team to resolve issues related to customer complaints
- Maintain awareness of current regulations and pharmaceutical industry compliance practices. Provide guidance to all levels of management regarding quality and regulatory compliance
- Ensure compliance with requirements including cGMP, OSHA, FDA. Create a safe working environment, enforce and monitor all safety procedures.

Invagen Pharmaceuticals

Sr. Manager Quality, Jan-2017 to Oct-2017

Direct and provide oversight of the entire Quality department maintaining control of diverse business operations; manage regulatory inspections, monitor financial planning, budget administration, human resources operations, and manage daily activities, effectively identifying and resolving issues. Establish and interpret policies and procedures that align with company vision, ensuring functionality of business operations and sustainable growth.

- Ensure all deviations and incidents are investigated thoroughly and a root cause analysis is completed for all deviations to avoid repetition in the future.
- Co-Ordinate the implementation of LIMS project for the Quality operation
- Act as point of contact for vendors to procure new instruments & PM programs; build and maintain effective vendor relationships, responding to inquiries and resolving issues.
- Oversee staffing and training for the department; evaluate performance, providing coaching and feedback, and implement programs to drive employee retention.
- Collaborate with senior leadership, attending meetings and representing the quality control interests concerning the implementation of plant operations.
- Evaluate operations, and atomize existing manual processes done, improving quality systems; and manage all regulatory inspections.
- Enhance the Quality policies as required, resulting in improved compliance status of the company.
- Member of the Project Eagle, aimed at reducing the expenses of the company by reviewing budget allocations across various departments.
- Provide guidance regarding the construction of new labs and requirements according to GMP regulations.

QC Manager, 2012 to 2017

Monitored and oversaw daily operations to ensure compliance with regulatory governmental agencies, implementing proper systems and controls. Managed all activities regarding finished products, raw materials and stability sections to ensure proper functioning, and developed strategic initiatives and action plans to achieve business objectives.

- Directed multiple effective quality control programs, monitoring and reducing the cost while ensuring alignment with high quality standards.
- Provided technical expertise to support the development of quality control testing methods and material specification for products manufactured by the division.
- Oversaw budget administration; ensured proper allocation and preparation of specification for laboratory equipment, supplies, and materials to meet testing schedules and quality standards.
- Managed site's Environmental Monitoring Program and monitored health and safety initiatives to ensure a safe working environment and proper handling of dangerous goods and substances.
- Served as a scientific and technical representative; acted as a liaison for the Division regarding technical matters and client relationship management.
- Received recognition and management appreciation for successful completion of multiple projects that enhanced laboratory functions.

Analytical Scientist-Quality Control, 2008 to 2012

Managed chemical evaluation of finished products, intermediate products, raw materials, reviewed analytical data, following test methods and relating SOP's. Completed testing on samples to ensure compliance with FDA and cGMP requirements in accordance with approved written procedures and specifications.

- Tested finished products, stability samples, raw materials, method validations and monitored the movement of hazardous materials within the facility to enforce compliance with local, state, and federal regulations regarding disposal.
- Successfully directed multiple small projects, utilizing a certain degree of creativity and latitude.
- Instrumentation included high levels of complexity and difficulty including GC, HPLC, UPLC, IC, UV, KF, ICP and ICP-MS.

PROFESSIONAL ASSOCIATIONS

Member of RAPS and Member of GPhA
Member of American Chemical Association
Member of Indian Pharmaceutical Congress

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

12/10/2025
Date

I, Ajay Vemula, **certify that as the designated representative for**

Aiping Pharmaceutical, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AV I am at least 21 years of age;
3. AV I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AV I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AV I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AV I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AV I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ajay Vemula

Print Name (First, Last)

AV.

Original Signature (electronic, copies or stamps not accepted)

12/10/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ajay Vemula

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/10/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, AJAY VEMULA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/10/2025

Date

Subscribed and Sworn to before me this 10 day of Dec. 2025.

Notary Public Signature

LJILJANA ZIVKOVIC
STATE OF NEW YORK
NOTARY PUBLIC
Qualified in Nassau County
01Z10005876
[Seal]
MY COMMISSION EXPIRES 4/19/2027

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Aiping Pharmaceutical, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 350 Wireless Blvd

City: Hauppauge State: NY Zip: 11788

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 631-465-4089 Website: www.aipingpharma.com

Licensing Company Email: compliance.aipingpharma@gmail.com

Section 2: Personal Information

First: Emma Middle: Qingbo Last: Li Xu

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 350 Wireless Blvd

City: Hauppauge State: NY Zip: 11788

Telephone: 631-465-4089 Email: compliance.aipingpharma@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
New York University		09/19 - 06/21	
Address	City	State	Zip
44 W 4th St	New York	NY	10012
Diploma/Degree obtained, if any			
Masters in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Dowling College		09/07 - 06/09	
Address	City	State	Zip
150 Idle Hour Blvd	Oakdale	NY	11769
Diploma/Degree obtained, if any			
Master's Degree in Finance			

School Name		From - To (MM/YY – MM/YY)	
Montclair State University		09/93 - 06/96	
Address	City	State	Zip
1 Normal Ave	Montclair	NJ	07043
Diploma/Degree obtained, if any			
Bachelor's Degree in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Guangzhou University		09/80 - 06/83	
Address	City	State	Zip
Guangdong Province, Guangzhou, China	Guangzhou	Guangdo	
Diploma/Degree obtained, if any			
Bachelor's Degree in Business			

School Name		From - To (MM/YY – MM/YY	
High School District 97		09/75 - 06/80	
Address	City	State	Zip
Guangdong Province, Guangzhou, China	Guangzhou	Guangdo	
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/08 - present	[redacted]	Cold Spring Harbor	NY	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AiPing Pharmaceutical, Inc.			2014 - Present
Business Address	**City**	**State**	**Zip**
350 Wireless Blvd,	Hauppauge	NV	11788
Phone	**Title**		
631-465-4089			
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

[redacted]

Career Summary

- Provides fiscal, strategic and operational leadership to reduce indebtedness and improve operating results.
- Expert in strategic planning and implementation – Guiding and directing an enterprise through substantial change management utilizing strong and effective strategic leadership.
- Revamped internal procedures and controls, reorganized/ reallocated staff and implemented best practices and performance monitoring systems in support of continuous improvement.

Functional Skill Areas

Strategic Planning | Entrepreneurial Leadership | Business Development
Revenue Growth | Organizational Change | Executive Development | Matrix Management

Areas of Impact

- Able to oversee all functions of the company concurrently, while assisting the board in carrying out important governing functions.
- Well-versed in various fields including marketing, cost management, and capital raising.

PROFESSIONAL EXPERIENCE

AiPing Pharmaceutical, Hauppauge, NY **2014 to present**
Sole Director
Participate in regular meetings with the Executive Staff.
Approve corporate activities and transactions including contracts and agreements; election of new corporate executives; asset purchases and sales and approval of new corporate policies.
Responsible for amending the corporation's bylaws or articles of incorporation.

A&Z Pharmaceutical Inc., Hauppauge, NY **1995 to present**
CEO / Chairwoman
Employ strong leadership skills to ensure efficient and effective utilization of corporate resources; provide the latest up-to-date market information to staff and members.

Direct and assist the Board in carrying out important functions such as strategic planning, and advise Board members on various matters; coordinate with Executive Staff to establish various company mission and vision statements, in addition to effective methods to achieve equilibrium between both.

- Plan, direct and control all functions of the company; monitor and evaluate the performance of different departments.
- Ensure that the firm develops a positive image in the market and offers the best products/services to the general public; monitor different marketing procedures and ensure that they are profitable for the organization.
- Supervise all fundraising programs of the firm and assist in planning several strategies.

Key Achievements

- Significantly improved the quality of inter- and intra-departmental communications, and made the processes more efficient.
- Maximized profitability by streamlining operations and reducing unnecessary costs.

EDUCATION

GuangZhou University (China), Bachelor's Degree in Business
Montclair State University (New Jersey), Bachelor's Degree in Accounting
Dowling College (New York), Master's Degree in Finance

BOARDS & MEMBERSHIPS

Board of Advisors, Meltzer, Lippe, Goldstein & Breitstone, LLP
Board of Directors, Manufacturing Consortium of Long Island

HONORS & AWARDS

Special Award for all around Excellence in Corporate Social Responsibility, Healthcare, Hospitals and Pharmaceuticals, City and State Reports

Honoree – Long Island Go Red for Women Luncheon

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

12/10/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Emma Li Xu

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/10/25

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Nassau

I, Emma Li Xu, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/10/25

Date

Subscribed and Sworn to before me this 10 day of December 2025.

Notary Public Signature

LJILJANA ZIVKOVIC
STATE OF NEW YORK
NOTARY PUBLIC
Qualified in Nassau County
01Z10005876
MY COMMISSION EXPIRES 4/19/2027
(Seal)

AiPing
Pharmaceutical, Inc.

December 30, 2025

To whomever it may concern,

This is to confirm the following list of Employees in AiPing Pharmaceutical, Inc:

- Ajay Vemula, President
- Justin McManus, VP Sales-Business Development
- Mohit Chudasma, Project Manager
- Michael McGuirk, Sr. Manager, National Accounts
- Daniel Pantaleon, ERP System Specialist
- Sudha Pantula, Assistant Manager, Regulatory-Labeling

Sincerely,
AiPing Pharmaceutical, Inc.

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Arvato USA LLC

Physical Address: 3303 E Holmes Rd

City: Memphis State: TN Zip: 38118

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (901) 521-6736 Website: www.bertelsmann.com

Name of Designated Representative (DR): Ryan Joseph Sharpley

Licensing Company Email: raymundo.gutierrez@arvato.com DR Email: ryan.sharpley@arvato.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Prescription medical devices	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distribut
■ Others: Clinics/Surgical		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YE to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Smith and Nephew

Address: 1450 East Brooks Road City: Memphis State: TN Zip: 38116

Name: Abbott

Address: 100 Abbott Park Road City: Abbott Park State: IL Zip: 60064

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Bertelsmann, Inc.

Corporation/Organization Name: Arvato USA LLC

Mailing Address: 3303 E Holmes Rd.

City: Memphis State: TN Zip: 38118

Telephone: (901) 521 6736 Email: raymundo.gutierrez@arvato.com

Contact Person Name: Raymundo Gutierrez

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Arvato USA LLC

Facility Name

Andreas Podwojewski

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/22/2025

Date

Board Use Only	Date Received: 10/30/25	Amount: $0 waive

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
ARVATO USA LLC
3303 E Holmes Rd
Memphis, TN 38118
Registration Number: 3021008900
FEI Number*: 3021008900
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Arvato USA LLC[6]
3303 E Holmes Rd
Memphis, TN US 38118
Owner/Operator Number: 10082727[7]

Official Correspondent:
Raymundo Gutierrez
3303 E Holmes Rd
Memphis, TN 38118
Phone: 1-901-6051363

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 11/03/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10082727&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10082727&OwnerOperatc

Arvato USA LLC
List of Corporate Officers

Name	Title	Address	e-mail	Percentage Ownership
Mitat Aydindag	President	51 Sawyer Road, Suite 620 Waltham, MA 02453	mitat.aydindag@arvato.com	0
Christopher Hohns	Chief Financial Officer	51 Sawyer Road, Suite 620 Waltham, MA 02453	christopher.hohns@arvato.com	0
Andreas Podwojewski	Executive Vice President	51 Sawyer Road, Suite 620 Waltham, MA 02453	andreas.podwojewski@arvato.com	0
Jacqueline Arana	Assistant Secretary	1745 Broadway New York, NY 10019	jacqueline.arana@arvato.com	0

Ownership Structure
Arvato USA LLC

Arvato USA LLC is 100% wholly owned by the entity Bertleslmann, Inc., 1745 Broadway New York, NY 10019. No corporate officer and/or member holds ownership in the entity.

Bertleslmann, Inc. is 100% wholly owned by the entity Bertelsmann SE & Co. KGaA, Carl-Bertelsmann-Straße 270 33335 Gütersloh. No corporate officer and/or member holds ownership in the entity.

Bertelsmann SE & Co. KGaA is a privately held Kommanditgesellschaft auf Aktien (KGaA; partnership limited by shares). 80.9 percent of the capital shares in Bertelsmann SE & Co. KGaA are held indirectly by foundations (Bertelsmann Stiftung, Reinhard Mohn Stiftung, BVG-Familienstiftung, BVG-Stiftung), and 19.1 percent are held indirectly by the Mohn family.

Christoph Mohn is the Ultimate Beneficial Owner (UBO)
Bertelsmann SE & Co. KGaA
Carl-Bertelsmann-Straße 270 33335 Gütersloh
Phone: [redacted]
Email: Christoph.mohn@bertelsmann.de

Arvato USA LLC
Organizational Chart



Bertelsmann SE & Co. KGaA
Carl-Bertelsmann-Straße 270
33335 Gütersloh
Phone: +49 (0) 5241-80-0
Email: Christoph.mohn@bertelsmann.de

Bertleslmann, Inc.
1745 Broadway
New York, NY 10019
Phone: 212-782-1074
Email: jennifer.harper@bertelsmann.com

Arvato USA LLC
3303 E Holmes Rd.
Memphis, TN 38118
Phone: (901) 521 6736
Email: jennifer.harper@bertelsmann.com

Bertelsmann SE & Co. KGaA is a privately held Kommanditgesellschaft auf Aktien (KGaA; partnership limited by shares). 80.9 percent of the capital shares in Bertelsmann SE & Co. KGaA are held indirectly by foundations (Bertelsmann Stiftung, Reinhard Mohn Stiftung, BVG-Familienstiftung, BVG-Stiftung), and 19.1 percent are held indirectly by the Mohn family.

Christoph Mohn is the Ultimate Beneficial Owner (UBO)

Bertelsmann SE & Co. KGaA
Carl-Bertelsmann-Straße 270
33335 Gütersloh
Phone: +49 (0) 5241-80-0
Email: Christoph.mohn@bertelsmann.de

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ARVATO USA LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF JUNE, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ARVATO USA LLC" WAS FORMED ON THE FIFTH DAY OF OCTOBER, A.D. 2007.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4435593 8300

SR# 20253071290

Authentication: 203946756

Date: 06-13-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Last Updated: 1/28/2026

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy-Manufacturer/Wholesaler/Distributor
County = All
Results = 1

Click here to return to the search page

1

Arvato USA LLC
3303 Holmes Rd
Memphis, TN 38118
Attn: Steve Krokowski
901-834-6710

Rank: Third Party Logistics

Facility License Number: 00007052
Status: Licensed
Date of Original Licensure: 10/04/2021
Date of Expiration: 11/30/2027
No Disciplinary Actions

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/25/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, LLC
1166 AVENUE OF THE AMERICAS
NEW YORK, NY 10036
Attn: NewYork.Certs@marsh.com Fax: 212-948-0500
CN101927909-STND-GAWU-25-26

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Greenwich Insurance Company	22322
INSURER B : N/A	N/A
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Arvato USA LLC
51 Sawyer Road, Suite 620
Waltham, MA 02453

COVERAGES **CERTIFICATE NUMBER:** NYC-012458004-00 **REVISION NUMBER:** 0

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			RGG943702222	07/01/2025	07/01/2026	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 250,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 4,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of insurance for 3303 East Holmes Rd., Memphis, TN 38118

CERTIFICATE HOLDER
Arvato USA LLC
51 Sawyer Road, Suite 620
Waltham, MA 02453

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA LLC
Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800198551

Application/License No. _____

ARVATO USA LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 3303 E HOLMES RD, Memphis, TN 38118-8101 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800, Plymouth, MN, 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 1, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of July, 2025.

APPLICANT/PRINCIPAL
ARVATO USA LLC

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY
Atlantic Specialty Insurance Company (US)

Surety Company's Representative

Loretta M. Jones, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Rachel A. Chaveriat

Witness Michelle Lute-Heatherly

Countersigned by:

Non-resident Agent License #527233

Nevada Resident Agent

[intact] INSURANCE

Power of Attorney

Surety Bond No: 800198551

Principal ARVATO USA LLC
Obligee Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: Loretta M. Jones each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 11th day of July, 2025.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

[intact] specialty solutions
INSURANCE

Atlantic Specialty Insurance Company

Period Ended 12/31/2024

Dollars displayed in thousands

Admitted Assets	
Investments	
Bonds	$ 2,894,094
Preferred Stocks	-
Common Stocks	987,702
Mortgage Loans	-
Real Estate	-
Contract Loans	-
Derivatives	-
Cash, Cash Equivalents & Short Term Investments	383,175
Other Investments	36,178
Total Cash & Investments	4,301,149
Premiums and Considerations Due	350,792
Reinsurance Recoverable	60,063
Receivable from Parent, Subsidiary or Affiliates	11,764
All Other Admitted Assets	94,008
Total Admitted Assets	4,817,776

Liabilities and Surplus	
Liabilities	
Loss Reserves	$ 1,264,802
Loss Adjustment Expense Reserves	423,323
Total Loss & LAE Reserves	1,688,125
Unearned Premium Reserve	811,551
Total Reinsurance Liabilities	64,571
Commissions, Other Expenses, and Taxes due	75,922
Derivatives	-
Payable to Parent, Subs or Affiliates	-
All Other Liabilities	1,121,125
Total Liabilities	3,761,294
Capital and Surplus	
Common Capital Stock	9,001
Preferred Capital Stock	
Surplus Notes	
Unassigned Surplus	476,697
Other Including Gross Contributed	570,784
Capital & Surplus	1,056,482
Total Liabilities and C&S	4,817,776

State of Minnesota
County of Hennepin

I, Kara Barrow, Secretary of Atlantic Specialty Insurance Company do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company, on the 31st day of December, 2024, according to the best of my information, knowledge and belief.

Secretary

Subscribed and sworn to, before me, a Notary Public of the State of Minnesota on this 10th day of March, 2025.

Notary Public

KERRI RIECHERS
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2030

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Arvato USA LLC — MDEG License # (if applicable): N/A

Physical Address: 3303 E Holmes Rd

City: Memphis — State: TN — Zip: 38118

Mailing Address (if different from physical address): Same as physical

City: — State: — Zip:

Telephone: — Website: www.bertelsmann.com

Licensing Company Email: raymundo.gutierrez@arvato.com

Section 2: Personal Information

First: Ryan — Middle: Joseph — Last: Sharpley

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITI[redacted] — Sex: ■ M ☐ F ☐ X

Mailing Address: 3303 E Holmes Rd.

City: Memphis — State: T N — Zip: 38118

Telephon[redacted] — Email: ryan.sharpley@arvato.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	☐	☑
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	☐	☐

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Notre Dame		08/07 - 01/12	
Address	**City**	**State**	**Zip**
400 Main Building	Notre Dame	IN	46556
Diploma/Degree obtained, if any			
Bachelors Degree			

School Name		From - To (MM/YY – MM/YY)	
Marshall High School		09/03 - 06/07	
Address	**City**	**State**	**Zip**
701 N. Marshall Ave.	Marshall	MI	49068
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 - present	[redacted]	Memphis	TN	[redacted]
From - To (MM/YY – MM/YY		City	State	
01/22 - 02/22		Memphis	TN	
From - To (MM/YY – MM/YY		City	State	
08/13 -01/22		Memphis	TN	
From - To (MM/YY – MM/YY		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Arvato USA LLC			08/24 - current	
Business Address		**City**	**State**	**Zip**
3303 E. Holmes Road		Memphis	TN	38118
Phone	**Title**		**Number of Employed Hours**	
901-618-6970	Site Director		2200	

Description of Duties

Responsible for client's KPIs, ISO certifications, record keeping and quality, employee retention in medical device distribution.

Business Name			From - To (MM/YY – MM/YY)	
Maersk			10/17 - 08/24	
Business Address		**City**	**State**	**Zip**
4665 Distriplex Dr W		Memphis	TN	38118
Phone	**Title**		**Number of Employed Hours**	
901-618-8970	Site Director		14240	

Description of Duties

Site Director responsible for meeting client KPI's, maintaining FDA compliance, meeting company profitability targets, record keeping, and staff retention/growth in the health/wellness vertical.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	☐	☑

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Ryan Joseph Sharpley, certify that as the MDEG Administrator for

Arvato USA LLC,

that I (initial that you have read and meet the following requirements):

1. RJS Have a high school diploma or its equivalent;
2. RJS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RJS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RJS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Sharpley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/25

Date

Board Use Only	Date Received:

Scanned with CamScanner

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Arvato USA LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 3303 E Holmes Rd

City Memphis State Tn Zip 38118

Malling Address (if different from physical address) Same as physical

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email raymundo.gutierrez@arvato.com

Section 2: Personal Information

First Ryan Middle Joseph Last Sharpley

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 3303 E Holmes Rd.

City Memphis State TN Zip 38118

Telephon [redacted] Email ryan.sharpley@arvato.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Notre Dame		08/07-01/12	
Address	**City**	**State**	**Zip**
400 Main Building	Notre Dame	IN	46556
Diploma/Degree obtained, if any			
Bachelors Degree			

School Name		From - To (MM/YY – MM/YY)	
Marshall High School		09/03-06/07	
Address	**City**	**State**	**Zip**
701 N Marshall Ave	Marshall	MI	49068
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/Y		City	State	Zip
02/22 - present	[redacted]	Memphis	TN	[redacted]
From - To (MM/YY – MM/Y		City	State	
01/22 - 02/22		Memphis	TN	
From - To (MM/YY – MM/Y		City	State	
08/13 -01/22		Memphis	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Arvato USA LLC			08/24-current	
Business Address		**City**	**State**	**Zip**
3303 E Holmes Rd		Memphis	TN	38118
Phone	**Title**		**Number of Employed Hours**	
9016186970	Site Director		2200	

Description of Duties

Responsible for client KPIs, ISO certifications,record keeping and quality, employee retention in Medical Device distro. Our business has not managed drugs which is why I do not have any experience in dispensing/distro presc. drugs

Business Name			From - To (MM/YY – MM/YY)	
Maersk			10/17-08/24	
Business Address		**City**	**State**	**Zip**
4665 Distriplex Dr W		Memphis	TN	38118
Phone	**Title**		**Number of Employed Hours**	
9016186970	Site Director		14240	

Description of Duties

Site Director responsible for meeting client KPIs, maintaining FDA compliance, meeting company profitability targets, record keeping, and staff retention/growth in the health/wellness vertical.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ 09/08/2025

Original Signature (electronic, copies or stamps not accepted) Date

I, Ryan Joseph Sharpley, **certify that as the designated representative for**

Arvato USA LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RJS I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs. See Sec 7
4. RJS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RJS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RJS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RJS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ryan Sharpley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~09/08/2025~~ (RS) 10/17/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Sharpley

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~09/08/2025~~ (RS) 10/17/2025

Date

Please have this section completed in the presence of a Notary Public.

State of TN, ss. County of Shelby

I, Ryan Sharpley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/17/2025

Date

Subscribed and Sworn to before me this 17 day of October, 2025

Notary Public Signature

JAMIYA FITZGERALD STATE OF TENNESSEE NOTARY PUBLIC COMM. EXP. 4-[illegible]-2028 SHELBY COUNTY (Seal)

Arvato USA LLC
3303 E Holmes Rd.
Memphis, TN 38118

LIST OF INDEBTEDNESS

Full Name / Entity Name	Role/Relationship to Applicant	Title/Position	Nature of Influence or Involvement	Notes
Corporation Service Company	Agent	Registered Agent	Receives legal service of process on behalf of the company	No operational decision-making role
FedEx Corporation	Common Carrier	Logistics Provider	Provides final-mile delivery of packaged shipments	Exempt under delivery service clause
Ryan Sharpley	Employee	General Manager	Oversees day-to-day operations and staff	Direct influence over operations
Raymundo Gutierrez	Employee	Quality Manager	Provides advice on QMS implementation	Involved in regulatory compliance strategy
Evan Wiley	Employee	Operations Manager	Supervises warehouse staff and drug storage	Key responsibility in product handling
Mitat Aydindag	Member/Officer	President	Legal and financial decision-maker	Significant influence over business strategy and capital management
Christopher Hohns	Member/Officer	Chief Financial Officer	Legal and financial decision-maker	Significant influence over business strategy and capital management
Andreas Podwojewski	Member/Officer	Executive Vice President	Legal and financial decision-maker	Significant influence over business strategy and capital management
Maysa Dahdouli	Member/Officer	Senior Vice President, Taxes	Legal and financial decision-maker	Significant influence over business strategy and capital management
Christopher Benecke	Member/Officer	Secretary	Legal and financial decision-maker	Significant influence over business strategy and capital management
Jacqueline Arana	Member/Officer	Assistant Secretary	Legal and financial decision-maker	Significant influence over business strategy and capital management

Attachment

Facility Inspection Report

COPY

TENNESSEE DEPARTMENT OF HEALTH
BOARD OF PHARMACY
MANUFACTURER/WHOLESALER/DISTRIBUTOR
REPORT OF INSPECTION

Inspected by	Date	Phone No.
DEREK JOHNSTON	7/31/25	901-834-6710

This Inspection Satisfactory: Yes ☑ No ☐

☐ Opening ☐ Relocation ☐ Follow-up ☑ Periodic ☐ New Ownership

Licensee: ARVATO USA LLC

License No. 7052 Expiration Date 11/30/25

Mailing Address:

Physical Address: 3303 HOLMES RD MEMPHIS 38118

Manufacturer ☐ 3PL ☑ Distributor (Includes Medical Gases) ☐ Wholesaler ☐

Distributes drugs to: Community Pharmacists, Hospital Pharmacies, Wholesalers, Physicians, Veterinarians, Researchers

Other

DEA No. N/A

TN Cont. Sub. ☐

Last Theft/Loss Report N/A

Last DEA Inventory N/A

Managers Name: STEVE KRACKOWSKI

Pharmacist (if repackaging) N/A

Pharmacist License No. N/A

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		1. Certificate displayed
✓		2. Board's law book on hand
✓		3. Suitable size and construction to facilitate cleaning, maintenance, and proper operations.
✓		4. Storage area provides adequate lighting, ventilation, temperature, sanitation, humidity, space and equipment.
✓		5. Quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated.
✓		6. Maintained in a clean and orderly condition.
✓		7. Free from infestation by insects, rodents, birds, or vermin.

Compliance Yes	Compliance No	STORAGE
✓		1. Prescription drugs stored at "controlled" room temperature
✓		2. Appropriate manual electro mechanical or electronic temperature, humidity recording equipment, devices and/or logs.

Compliance Yes	Compliance No	SECURITY
✓		1. Access from outside premises shall be kept to a minimum and well controlled.
✓		2. Outside perimeter of the premises shall be well lighted
✓		3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.
✓		4. Alarm system equipment to detect entry after hours: provide suitable protection against theft and diversion; diversion that is facilitated or hidden by tampering with computers or electronic records.

Alarm type: SECURITY GATE, SECURITY GUARDS, KEY CARD ACCESS, PIN PAD, CAMERAS, MOTION DETECTORS

Business hours: 7-5:30 M-F

Compliance Yes	Compliance No	RECORD KEEPING
✓		1. Inventories of records of all transactions maintained to reflect:
✓		a. Source of drugs – names and address of seller/or transferor.
✓		b. Address of location shipped from
✓		c. Identity/quantity of drugs received and distributed or disposed of
✓		d. Dates of receipt of distribution or other disposition of the drugs.
✓		2. Inventories and records maintained so as to be readily retrievable for at least 2 years.

DISCUSSED

Compliance Yes	Compliance No	WRITTEN POLICIES AND PROCEDURES ON HAND INCLUDE:
✓		1. Oldest approved stock of prescription drug products distributed first. CLIENT BASED
✓		2. Procedures for handling recalls and withdrawals of prescription drugs.
✓		3. Procedures to remove defective or potentially defective drugs from market. CLIENT BASED
✓		4. Procedure to protect against and handle crisis that affects security or operation in the event of a strike, flood, or other natural disaster or national emergency.
✓		5. Procedures to insure that any outdated prescription drugs shall be segregated from other drugs – either returned to manufacturer or destroyed.
✓		6. Procedures to identify damaged goods upon receipt to prevent further distribution. CLIENT BASED
✓		7. Procedures outline education and/or experience for qualification for each job title at the facility.

I Renae Edwards, Manager, do hereby acknowledge and understand all notations made on this report and confirm that within 30 days I will notify the Board of Pharmacy in writing of the correction of any and all deficiencies noted above.

Response Required Yes ☐ No ☑

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ASCENT PHARMACEUTICALS, INC.

Physical Address: 400 SOUTH TECHNOLOGY DRIVE

City: CENTRAL ISLIP State: NY Zip: 11722

Mailing Address (if different from physical address): SAME AS ABOVE

City: _____ State: _____ Zip: _____

Telephone: 631-851-0550 Website: _____

Name of Designated Representative (DR): VENKATASUBRAMANIAN JAYARAMAN

Licensing Company Email: VENKAT@ASCENTPHARM.COM DR Email: VENKAT@ASCENTPHARM.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/15/2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: UNIVAR SOLUTIONS USA
Address: 200 DEAN SIEVERS PLACE City: MORRISVILLE State: PA Zip: 19067

Name: BRENNTAG SPECIALTIES LLC
Address: 186 WOOD AVE S City: ISELIN State: NJ Zip: 08830

Name: COLORCON, INC
Address: 420 MOYER BLVD City: WEST POINT State: PA Zip: 19486

Name: ASHLAND INC
Address: 1111 HERCULES ROAD City: HOPEWELL State: VA Zip: 23860

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEW YORK
Parent Company (if any):
Corporation/Organization Name: ASCENT PHARMACEUTICALS INC.
Mailing Address: 400 SOUTH TECHNOLOGY DRIVE
City: CENTRAL ISLIP State: NY Zip: 11722
Telephone: 631-851-0550 Email: VENKAT@ASCENTPHARM.COM
Contact Person Name: VENKATASUBRAMANIAN JAYARAMAN

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ASCENT PHARMACEUTICALS INC

Facility Name

VENKATASUBRAMANIAN JAYARAMAN

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/15/2025

Date

Board Use Only	Date Received: 12/22/25	Amount: $1000cc

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Ascent Pharmaceuticals**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Ascent Pharmaceuticals Inc	3009518416	080938961	ANALYSIS; LABEL; MANUFACTURE; PACK;	400 S Technology Dr, Central Islip, New York (NY) 11722, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Thursday, Jan 1, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Owners

Name: Hetero FZCO, Dubai, UAE
Type of Owner: Corporation
Federal Employer Identification #: 00-0000000
Address: PO Box 54738
Dubai
United Arab Emirates
Ownership: 51%

Name: Sai Karuna Industrys Ltd.
Type of Owner: Corporation
Federal Employer Identification #: 00-0000000
Address: Plot No 389, Road 22/B Madhapur Road, Jubilee Hills Check-Post
Hyderabad
India
Ownership: 16%

Name: Genarete Holding & CO
Type of Owner: Corporation
Federal Employer Identification #: 81-3507510
Address: 50 landview Dr
Dixhills, NY 11746
Ownership: 8%

Name: Alphamed Holdings Inc.
Type of Owner: Corporation
Federal Employer Identification #: 81-2934086
Address: 300 South Technology Drive
Central Islip, NY 11722
Ownership: 25%

PRESIDENT: SUDHAKAR VIDIYALA

CFO: VASU SABBELLA

VICE PRESIDENT QUALITY ASSURANCE: VENKATASUBRAMANIAN JAYARAMAN

QA DIRECTOR: PRAVEEN BALGURI

DIRECTOR PROJECT: MEGHANA VIDIYALA

VICE PRESIDENT DEA COMPLIANCE: CORI RIZMAN

HEAD OF ENGINEERING: GARY GRAU

DIRECTOR, HUMAN RESOURCES: GREGORY GIACALONE

DIRECTOR MANUFACTURING: RAGHOTHAM KATLA

VP, RESEARCH & DEVELOPMENT: SRIDHAR GUMDAVELLI

DIRECTOR, PACKAGING CHARANJIT SINGH

ASSOCIATE DIRECTOR, SUPPLY CHAIN: HAMMAD HUSSAIN

ASSOCIATE DIRECTOR, AR&D: HARISH CHERIVIRALA

DIRECTOR QUALITY CONTROL: DAVIES KOLLANUR KOCHUNNI

State of New York
Department of State } ss:

I hereby certify, that the Certificate of Incorporation of ASCENT PHARMACEUTICALS INC. was filed on 08/31/2011, with perpetual duration, and that a diligent examination has been made of the Corporate index for documents filed with this Department for a certificate, order, or record of a dissolution, and upon such examination, no such certificate, order or record has been found, and that so far as indicated by the records of this Department, such corporation is an existing corporation. I further certify the following:

A Biennial Statement was filed 09/03/2013.

A Certificate of Amendment was filed on 07/11/2016.

Certificate of Change was filed on 08/02/2016.

A Certificate of Amendment was filed on 08/11/2016.

A Biennial Statement was filed 01/18/2017.

A Biennial Statement was filed 03/07/2018.

Certificate of Change was filed on 03/12/2018.

A Biennial Statement was filed 02/18/2020.

I further certify that no other documents have been filed by such corporation.



***

Witness my hand and the official seal of the Department of State at the City of Albany, this 19th day of February two thousand and twenty.

Brendan C. Hughes
Executive Deputy Secretary of State

202002200118 * 9I

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-26

NAME OF SUPERVISOR
VENKATASUBRAMANIAN JAYARAMAN

THIS IS TO CERTIFY

ASCENT PHARMACEUTICALS INC.
400 SOUTH TECHNOLOGY DR.
CENTRAL ISLIP, NY 11722

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF DECEMBER, 2023.
THIS CERTIFICATE EXPIRES ON THE THIRTIETH DAY OF NOVEMBER, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

035312

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

NEW YORK STATE DEPARTMENT OF HEALTH
CONTROLLED SUBSTANCE LICENSE

Legal Name or Operator:
ASCENT PHARMACEUTICALS INC

ASCENT PHARMACEUTICALS INC
400 SOUTH TECHNOLOGY DRIVE
CENTRAL ISLIP, NY 11722

Class: 080
ANALYTICAL LABORATORY

Licensed Location:
ASCENT PHARMACEUTICALS INC
400 SOUTH TECHNOLOGY DRIVE
CENTRAL ISLIP, NY 11722

Schedule:
I II III IV V

HAS GIVEN SATISFACTORY EVIDENCE THAT ALL QUALIFICATIONS AS REQUIRED BY ARTICLE 33 OF THE PUBLIC HEALTH LAW AND PART 80 OF THE ADMINISTRATIVE RULES AND REGULATIONS HAVE BEEN MET AND IS HEREBY GRANTED A LICENSE TO ENGAGE IN CONTROLLED SUBSTANCE ACTIVITY IN THE STATE OF NEW YORK IN THE CLASSIFICATION STATED ABOVE.

LICENSE #: 0800350
EFFECTIVE: Jan 17 2024
EXPIRES: Jan 16 2026

JAMES V. McDONALD, M.D., M.P.H.,
COMMISSIONER OF HEALTH

TO BE PERMANENTLY DISPLAYED AT THE LICENSED SITE

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0448503	06-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5,L	MANUFACTURER	05-01-2025

ASCENT PHARMACEUTICALS, INC
ATTN: CORI RIZMAN
400 S TECHNOLOGY DR
CENTRAL ISLIP, NY 117224402

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0448503	06-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5,L1	MANUFACTURER	05-01-2025

ASCENT PHARMACEUTICALS, INC
ATTN: CORI RIZMAN
400 S TECHNOLOGY DR
CENTRAL ISLIP, NY 117224402

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RA0448503	06-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5,L	MANUFACTURER	05-01-2025

ASCENT PHARMACEUTICALS, INC
ATTN: CORI RIZMAN
400 S TECHNOLOGY DR
CENTRAL ISLIP, NY 117224402

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
9801 9150 9250 9300 9143 9652 9193 2012 8112 9780 1100 1205 1724 2010 7370 9050 9220

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K40667143

Application/License No. _____

Ascent Pharmaceuticals Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
400 S TECHNOLOGY DR, Central Islip, NY, 11722-4402, US, as
(Address of Applicant/Principal)
PRINCIPAL, and Westchester Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of PA
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
436 Walnut Street, WA10H, PHILADELPHIA, PA, 19106-3703, US as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 24, 2025.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

Commonwealth of Pennsylvania
County of Philadelphia)

On October 28th, 2025 before me, Karen E. Brandt, Notary Public
(insert name and title of the officer)

personally appeared Barbara Duggan, attorney in fact,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in her authorized capacity, and that by her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the Commonwealth of Pennsylvania that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Commonwealth of Pennsylvania - Notary Seal
KAREN E. BRANDT, Notary Public
Philadelphia County
My Commission Expires September 26, 2026
Commission Number 1227734

Signature Karen E Brandt (Seal)

WESTCHESTER FIRE INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2024

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash, Cash Equivalents, and ST Investments	$ 8,573	Outstanding Losses and Loss Expenses	$ -
United States Government, State and Municipal Bonds	54,582	Reinsurance Payable on Losses and Expenses	-
Other Bonds	9,682	Unearned Premiums	-
Stocks	-	Ceded Reinsurance Premiums Payable	-
Other Invested Assets	3,684	Other Liabilities	203,693
TOTAL INVESTMENTS	76,521	TOTAL LIABILITIES	203,693
Investments in Affiliates	-	Capital Stock	5,000
Premiums Receivable	-	Paid-In Surplus	40,960
Other Assets	184,587	Unassigned Funds	11,455
		SURPLUS TO POLICYHOLDERS	57,415
TOTAL ADMITTED ASSETS	$ 261,108	TOTAL LIABILITIES AND SURPLUS	$ 261,108

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2024, investments with a carrying value of $11,871,045 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Vigilant Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2024.

Sworn before me this March 20, 2025

Senior Vice President

Notary Public

August 8, 2027
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Notary Public
Philadelphia County
My commission expires August 8, 2027
Commission number 1235745
Member, Pennsylvania Association of Notaries

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28th day of October, 2025.

APPLICANT/PRINCIPAL

Ascent Pharmaceuticals Inc.

Authorized Representative

Vasu Sabbella, CFO

SIGNED and SEALED in the presence of:

Witness Dapeng Zhang

Witness MD HOSSAIN

SURETY COMPANY

Westchester Fire Insurance Company

Barbara Duggan
Surety Company's Representative

Barbara Duggan, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Lindsay Ward

Witness Frances Bonner

Countersigned by:

N/A
Nevada Resident Agent

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Donna Barchman, Frances Bonner, Karen Brandt, Sharon Dean, Barbara Duggan, Rashidah Hasan, Craig Gortner, Alexis Miller, Maria Siu, Rupert Swindells and Lindsay Ward of Philadelphia, Pennsylvania and Mary-Ann Goglia of Bradenton, Florida----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **25th** day of **September, 2024**.

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **25th** day of **September, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Albert Contursi
Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this 28th day of October 2025.

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903- 3493 Fax (908) 903- 3656 e-mail: surety@chubb.com

DocuGard #04546 contains a security pantograph, blue background, heat-sensitive ink, coin-reactive watermark, and microtext printing on border.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ASCENT PHARMACEUTICALS INC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 400 SOUTH TECHNOLOGY DRIVE

City CENTRAL ISLIP State NY Zip 11722

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First VENKATASUBRAMANIAN Middle _____ Last JAYARAMAN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Addres[redacted]

City ISLIP TERRACE State NY Zip [redacted]

Telephor[redacted] Email VENKAT@ASCENTPHARM.COM

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St.Joseph's Higher Secondary School		04/91-04/93	
Address	City	State	Zip
Tiruppapuliyur,Cuddalore,Tamilnadu,INDIA	Cuddalore	TN	607002
Diploma/Degree obtained, if any			
12th Grade			

School Name		From - To (MM/YY – MM/YY)	
Periyar Goverment college		04/93-04/96	
Address	City	State	Zip
Devanampattinam,Cuddalore,Tamilnadu,INDIA	Cuddalore	TN	607001
Diploma/Degree obtained, if any			
Bachelor of Science in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Jamal Mohamed college		04/96-04/98	
Address	City	State	Zip
7, Race Course Road, Khaja Nagar, Tiruchirappalli, Tamil Nadu	Trichirappalli	TN	620020
Diploma/Degree obtained, if any			
Master of Science in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16- current	[redacted]	ISLIP TERRACE	NY	[redacted]
08/13-11/16		HAUPPAUGE	NY	
01/12-07/13		HOLTSVILLE	NY	
06/11-12/11		DEER PARK	NY	
04/11-06/11		HAUPPAUGE	NY	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

ASCENT
PHARMACEUTICALS, INC.

Job Description

Employee Name: **Mr. Venkatasubramanian Jayaraman**

Designation : **Vice President -Head Quality Assurance**

Experience : **26 years +**

Roles and Responsibilities:

- Reports directly to the President& CEO.
- Responsible to review, identify the gaps within the system during routine monitoring and recommend to management for necessary improvements in the identified areas.
- Review Change Controls, Deviations, OOS observed during analysis and approve the same.
- Review and Control of Complaints, ADR, FAR and Recall.
- Conduct PQMR every quarterly and keep updating to the Management on status of Quality of facility.
- Familiar with current GMP practices and upgradation of current FDA and USP guidance to ensure compliance all the time.
- Directs and manages the entire operations of Product Development, Analytical, Manufacturing and Packaging. Responsible for the design and implementation of policies and procedures to ensure that quality standards are met during production and manufacturing.
- Coordinates inspection of the organization and contract facilities, and develops procedures to ensure regulatory compliance.
- Oversees testing of processes and products.
- Ensure all requirements are adequately verified. Performs a variety of tasks.
- Leads and directs the work of others.
- Facilitating the Audits belongs to customer and FDA audits and ensures compliance all the times.

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
ASCENT PHARMACEUTICALS,INC			02/14 to current	
Business Address		**City**	**State**	**Zip**
400 SOUTH TECHNOLOGY DRIVE		CENTRAL ISLIP	NY	11722
Phone	**Title**		**Number of Employed Hours**	
631-881-4614	VP-Head Quality Assurance		40	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/15/2025
Date

I, VENKATASUBRAMANIAN JAYARAMAN, **certify that as the designated representative for**

ASCENT PHARMACEUTICALS INC.400 SOUTH TECHNOLOGY DRIVE,CENTRAL ISLIP,NY-11722,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VJ I am at least 21 years of age;
3. VJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

VENKATASUBRAMANIAN JAYARAMAN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

VENKATASUBRAMANIAN JAYARAMAN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Suffolk

I, VENKATASUBRAMANIAN JAYARAMAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/15/2025

Date

Subscribed and Sworn to before me this 15th day of October 2025

Notary Public Signature

PATRIA PERALTA
Notary Public, State of New York
Reg. No. 01PE6293071
Qualified in Suffolk County
Commission Expires NOV 18, 2025

(Seal)

Ascent Pharmaceuticals, Inc.-Head Count

Last Name	First Name
Acharya	Bhanu
Adapa	Krishna Leela
Aftab	Arslan
Aguilar Fuentes	Kevin
Aguilar Gonzalez	Natalie
Ahmed	Abrar
Ahmed	Shahin
Akhtar	Shaheena
Akter	Nasrin
Akula	Venkata Krishna
Alam	Shamsul
Alexander	Teena
Almendarez	Irene
Almendarez	Cindy
Altaf	Farrukh
Alvizures	Jonnathan
Anumolu	Venkata Sai
Anwar	Muhammad Zohaib
Anwar	Muhammad Zeshan
Argueta	Mayra
Argueta	Jose
Argueta	Claudia
Argueta Flores	Cesar
Argueta Guevara	Ruben
Arias	Josue
Arias	Adriana
Arifadil	Syed Mohammad
Aris	Evens
Arshad	Kamran
Arshad	Aqsa
Aryal	Dasharath
Ascarcena Mosquera	Gabriela Celia
Asif	Saad
Atalia	Hetal
Avila	Henry

Avila Buezo	Stephany
Ayub	Aqib
Azhar	Awais
Badiouzzaman	Shaik
Balguri	Praveen
Bandi	Rama Krishna
Banegas	Riccy
Banos	Liliana
Basnet	Subash
Basnet	Dinesh
Begum	Ferdousi
Benitez De Salvador	Kenia
Bhat	Barun
Bhattarai	Ganga
Bhattarai	Kashi
Bhuwanji	Shantosh
Bista	Ram
Bitra	Chaithanya
Bodigam Ravinder Mounika	FNU
Bohara	Prakash
Bonilla Ramos	Editrudes
Bonthu	Jithendra
Boodhai	Roopawattie
Budhathoki	Rajan
Cabrera	Denis
Calix	Darlyng
Carranza De Castaneda	Gloria
Castro Locon	Aldo
Chatti	Aruna
Chaudhry	Amara
Chaudhry	Samina
Chaudhry	Muhammad
Cherivirala	Harish
Chhantel Thapa	Purna
Chhantyal	Tika
Chhantyal	Sita Kumari
Chhetri	Ashok
Chhetri	Mohan

Chilukoti	Varun
Chittireddy	Vineetha
Chollety	Vijay Kumar
Clairvoyant	Exilien
Colon Saez	Carolina
Cornejo	Yasmin
Cruz Salmeron	Maria
Cruz Saravia	Sindy
Damarla	Janvitha Sai
Danish	Muhammad
Dash	Rubel
Davies	Jissy
Davila Lopez	Brenda
Dayaka	Sreedevi
De Lucia	Katie
Deekonda	Prerana
DeLeon	Jannette
Desmangles	Jodely
Devineni	Umesh Chandra Chowdary
Dhakal	Sangita
Divadari	Hareesh
Dorvil	Berman
El-Karimi	Ahmed
Escobar Lemus	Jefferson
Espinal	Mirna
Esquivel	Alicia
Estrada	Maria
Exantus	Wender
Fabian	Gonzalez Manuel
Fabian Rubio	Analfi
Faizullah	Mehreen
Flores	Miguel
Flores	Andrea
Flores	Gaby
Flores	Eulalia
Franco-Berrios	Maria
Fuentes	Digna
Fuentes	Yenis

Galarza	Freddy
Gangaraju	Bhavani
Garcia	Santos
Garcia	Alisson
Garcia Amaya	Micsin
Garcia Martinez	Sissy
Gautam	Arjun
George	Aswin
Georges	Joel
Ghatri	Kalpana
Giacalone	Gregory
Giri	Mahendra
Gomez	Mercedes
Gomez Jr	Omar
Gosh	Krishno
Granados	Samuel
Granados Argueta	Wendy
Grau	Gary
Gregorio Marquirez	Andres
Guerrier	Sarafina
Guevara	Edinson
Gumudavelli	Sridhar
Gundlapalli	Saipavani
Gurram	Durga Bhavani
Gurram	Dasarath
Guzman	Jose
Handa	Neha
Haque	Lata
Haque	Zannatun
Haque	Sabina
Haque	Sayed K
Haris	Muhammad
Haseeb	Muhammad
Hashemi	Karima
Hayat	Yawar
Hernandez	Mario
Hernandez	Virginia
Hernandez	Celia

Hernandez	Floriselda
Hernandez Canales	Erick
Hoque	Flave
Hossain	MD
Hossain	Enayat
Hussain	Hammad
Iftikhar	Jawad
Iqbal	Khaled
Islam	Shiful
Islam	Azizul
Jabed	Chowdhury
Jacinto	Carlos
Jacinto Santos	Luis
Jagabattula	Maheshwari
JaggavarapuPhani	Kumar
Jampalli	Thriveni
Jayaraman	Venkatasubramanian
Jean Louis	Bony
Joya	Maximino
Kabir	Khandaker MD
Kandel	Shalik
Kandel	Khima
Kandel	Chandriswor
Karki	Gopal
Karki	Sarita
Karumanchi	Sreekanth
Katla	Raghotham
Kayani	Arham
KC	Bishnu
Khalid	Waqas
Khan	Urooj
Khan	Shahadat
Khan	Naveed
Khan	Sumaid
Khan	Afaq
Khandoker	MD Asaduzzaman
Khatri	Tika
Khatri	Prem

Khatri	Narendra
Khurana	Ankur
Kollanur Kochunni	Davies
Kommareddy	Sindhu Reddy
Kondaveeti	Sahithi
Lal	Madan
Lamichhane	Bishal
Lamichhane	Bishwo
Laureano	Yajaira
Leigue	Paola
Lekkala	Vamshi Krishna
Locon	Adonis
Locon	Yeimy
Lopez Vargas	Maryuri
Lovo	Justin
Madan	Shobhit
Mahajan	Arti
Majid	Abdul
Maldonado	Celvin
Maniruzzaman	Md
Manosalvas Azacata	Mireya
Marcellus	Jean Robert
Marquez	Maria
Marquez Pereira	Glenda
Martinez	Ana
Martinez	Cindy
Martinez	Julia
Martinez Claros	Karen
Mazariego	Ana
Medrano	Meerlyn
Mehra	Anu
Mejia	Santos
Mejia	Norma
Mejia Hernandez	Mary
Miah	Mohammed
Michelet	Pierre Louis
Moktan	Sunlal
Molina Velasquez	Raquel

Moran	Delmy
Moreno	Wilber
Moreno	Oscar
Mufti	Nazif
Muthyala	Renuka
Nakkala	Nissi
Nanavath	Shivaram
Nath	Haradhon
Nawaz	Luqman
Nekkalapudi	Arjuna Rao
Nerio	Ismelda
No Name Given	Vikas
Noel	Jinsky
None	Akshay
Noolu	Prasant
Nusum	Gayathri
Padidala	Kiran Kumar
Pakanati	Amulya Reddy
Pallavi	Pallavi
Panchal	Nilamben
Panchana	Jimmy
Pandey	Tulasi Ram
Pandey	Saurav
Pant	Ganesh
Parra	Javier
Patel	Vraj
Patel	Rakeshkumar
Patel	Hardikkumar
Patel	Hiren
Payero Quinones	Victor
Payero Quinones	Magdeline
Pennabadi	Swapna
Peralta	Abel
Peralta	Alicia
Persaud	Rohanie
Petit	Jimmy
Philip	Angela
Pingali	Venkata Mahesh Gautham

Portillo	Carmen
Potlapalli	Tanuj
Pun	Dibina
Pun	Diwas
Pun Gharti	Rajani
Puri	Megha
Puri	Tankaraj
Puri	Laxman
Puri	Debendra
Quintanilla	Marila
Rahman	Mohammad
Rahman	MD Mostafijar
Rai	Robin
Railla	Sravani
Ramirez De Turcios	Daysi
Ramos Andrade	Karla
Rathi	Siddhant
Ravi Kumar	FNU
Razzak	MD
Richard	Wadley
Richard	Bernadette
Rijal	Liladhar
Rivas	Ramon
Rivas	Evelin
Rizman	Cori
Rodriguez	Leonel
Rodriguez	Olga
Rodriguez	Emerson
Roman	Jenifer
Romero	Guillermo
Romero	Celia
Romero Santamaria	Malena
Roque	Kenia
Rosales	Reina
Roy	Bijit
Ruan	Sheng
Rubio Viera	Brayan
Ruiz	Marco

Sabbella	Vasu
Sabbella	Abhilash Reddy
Saini	Anmol
Sajjad	Kashmala
Sampeta	Srinivasu
Sanchez	Carolina
Sanchez Diaz	Rafael
Sandineni	Prashanth
SapiReddi	Siva Subramanyam
Sastoque	Diego
Sayeed	MD Abu
Schinkel	Thomas
Sentaus	Serge
Shafiq	Mian Samran
Sharma Adhikari	Upendra
Shenai	Manisha
Sherpa	Karma
Shrestha	Barshad
Siddabathuni	Kalyan Venkata Narayana
Siddiqui	Zeeshan
Silwal	Sanubabu
Singh	Baldev
Singh	Maninder
Singh	Tejpal
Singh	Charanjit
Sorto	Rodolfo
Sorto	Bessy M
Sorto Reyes	Maxely
Subedi	Shyam
Subir	Farnendu
Sudireddy	Bharath Reddy
Sunar	Rajesh
Sundar	Teja
Syeda	Sana
Talukder	MD Zahangir
Tamang	Kamal
Tamang	Kul Bahadur
Tamang	Bir Bahadur

Tamber	Jagjot
Teegala	Arpitha Rao
Teepireddy	Suneel
Tercero	Bessy
Thapa	Pramod
Thelisma	Orisma
Thelisma	Alexandra
Thokar	Kristal
Thomas	Sherly
Tobar	Glenda
Tula	Sneha
Turcios	Adilia
Turcios	Vanessa
Turcios	Jason
Tusher	Hasibur Rahaman
Uddin	Mohammad
Urrea	Jose
Vaddeswaram	Ashok Babu
Valdez	Fernando
Vankayala	Radhakrishna
Varghese	Thomas
Varshney	Anjali
Vasconez	Maria
Vasquez	Jaime
Velasquez	Rosa
Vemulapalli	Viswas Rao
Ventura Argueta	Yolanda
Vidiyala	Sudhakar
Vidiyala	Meghana
Wazed	Md
Yadav	Suresh
Yalavarthi	Lasya Chowdary
Yousaf	Imran
Zaldivar	Erika
Zhang	Dapeng
Zhunio	Cesar
Zuleta	Xiomara
Zuniga	Ariel

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02656	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Blueprint Medicines Corporation

Physical Address: 45 Sidney Street

City: Cambridge State: MA Zip: 02139

Mailing Address (if different from physical address): 45 Sidney Street

City: Cambridge State: Massachusetts Zip: 02139

Telephone: (617) 374-7580 Website: https://www.blueprintmedicines.com/

Name of Designated Representative (DR): Paul Skerker

Licensing Company Email: info@blueprintmedicines.com DR Email: pskerker@blueprintmedicines.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies & Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

November 18, 2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Aventis Inc.

Corporation/Organization Name: Blueprint Medicines Corporation

Mailing Address: 45 Sidney Street

City: Cambridge State: Massachusetts Zip: 02139

Telephone: 908-981-5000 Email: info@blueprintmedicines.com

Contact Person Name: Paul Skerker

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	x	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Blueprint Medicines Corporation

Facility Name

Ariel Hurley

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

November 18, 2025

Date

Board Use Only	Date Received: 12/22/25	Amount: $1000-ck 4959

Description of Operations

Blueprint Medicines Corporation is a privately held Corporation and a Virtual Manufacturer (NASDAQ: BPMC), located in Cambridge, MA. Blueprint's product is manufactured by a Contract Manufacturer and will be distributed to specialty pharmacies and specialty distributors by a Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state.

We are using the following contract manufacturers to produce our product:

Juniper Pharma Services, Ltd. (Catalent Nottingham)
8 Nottingham Business Park, Orchard Place,
Nottingham, NottinghamShire NG8 6PX, United Kingdom (GBR)
+44 (0)115 871 8888
FDA Establishment No: 3005680952

Pharma Packaging Solutions (Tjoapack)
341 JD Yarnell Industrial Parkway
Clinton, TN 37716
FDA Establishment Number: 3002763532

Patheon Inc.
2100 Syntex Court Mississauga
Ontario Canada L5N 7K9
FDA Establishment Number: 3000264888

Packaging CMO: Andersonbrecon Inc d/b/a PCI of Illinois
4545 Assembly Drive
Rockford, IL 61109
FDA Establishment No: 1421377

Product Description
Juniper Pharma Services, Ltd., Patheon Inc, Andersonbrecon, and Pharma Packaging Solutions to manufacture and package Blueprint's product. At no time do these manufacturers own the product, contract with Blueprint's customers, invoice, nor sell Blueprint's product. Blueprint's product is not a Controlled Substance.

Labeler Code:
72064

Third Party Logistic information:
Integrated Commercialization Solutions LLC
420 International Blvd. Suite 500
Brooks, KY 40109

Blueprint's hours of operation are 8:30 am – 5:30pm EST Monday through Friday.

/ NDC (index.cfm)

National Drug Code Directory

Current through November 13, 2025

You have searched Finished drug products

Search Results: *'blueprint'*

Back to Search Page () | Search Again ()

CSV Excel

Display All records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
Ayvakit	72064-110-30	100 mg/1	TABLET, FILM COATED	ORAL	NDA212608	Blueprint Medicines Corporation	72064-110	avapritinib	AVAPRITINIB	HUMAN PRESCRIPTION DRUG	01/09/2020	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (72064-110-30)	Bile Salt Export Pump Inhibitors [MoA], Breast Cancer Resistance Protein Inhibitors [MoA], Cytochrome P450 2C9 Inhibitors [MoA], Kinase Inhibitor [EPC], Multidrug and Toxin Extrusion Transporter 1 Inhibitors [MoA], Multidrug and Toxin Extrusion Transporter 2 K Inhibitors [MoA], P-Glycoprotein Inhibitors [MoA], Tyrosine Kinase Inhibitors [MoA]	N/A

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
Ayvakit	72064-120-30	200 mg/1	TABLET, FILM COATED	ORAL	NDA212608	Blueprint Medicines Corporation	72064-120	avapritinib	AVAPRITINIB	HUMAN PRESCRIPTION DRUG	01/09/2020	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (72064-120-30)	Bile Salt Export Pump Inhibitors [MoA], Breast Cancer Resistance Protein Inhibitors [MoA], Cytochrome P450 2C9 Inhibitors [MoA], Kinase Inhibitor [EPC], Multidrug and Toxin Extrusion Transporter 1 Inhibitors [MoA], Multidrug and Toxin Extrusion Transporter 2 K Inhibitors [MoA], P-Glycoprotein Inhibitors [MoA], Tyrosine Kinase Inhibitors [MoA]	N/A
Ayvakit	72064-125-30	25 mg/1	TABLET, FILM COATED	ORAL	NDA212608	Blueprint Medicines Corporation	72064-125	avapritinib	AVAPRITINIB	HUMAN PRESCRIPTION DRUG	06/16/2021	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (72064-125-30)	Bile Salt Export Pump Inhibitors [MoA], Breast Cancer Resistance Protein Inhibitors [MoA], Cytochrome P450 2C9 Inhibitors [MoA], Kinase Inhibitor [EPC], Multidrug and Toxin Extrusion Transporter 1 Inhibitors [MoA], Multidrug and Toxin Extrusion Transporter 2 K Inhibitors [MoA], P-Glycoprotein Inhibitors [MoA], Tyrosine Kinase Inhibitors [MoA]	N/A

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
Ayvakit	72064-130-30	300 mg/1	TABLET, FILM COATED	ORAL	NDA212608	Blueprint Medicines Corporation	72064-130	avapritinib	AVAPRITINIB	HUMAN PRESCRIPTION DRUG	01/09/2020	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (72064-130-30)	Bile Salt Export Pump Inhibitors [MoA], Breast Cancer Resistance Protein Inhibitors [MoA], Cytochrome P450 2C9 Inhibitors [MoA], Kinase Inhibitor [EPC], Multidrug and Toxin Extrusion Transporter 1 Inhibitors [MoA], Multidrug and Toxin Extrusion Transporter 2 K Inhibitors [MoA], P-Glycoprotein Inhibitors [MoA], Tyrosine Kinase Inhibitors [MoA]	N/A
Ayvakit	72064-150-30	50 mg/1	TABLET, FILM COATED	ORAL	NDA212608	Blueprint Medicines Corporation	72064-150	avapritinib	AVAPRITINIB	HUMAN PRESCRIPTION DRUG	06/16/2021	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (72064-150-30)	Bile Salt Export Pump Inhibitors [MoA], Breast Cancer Resistance Protein Inhibitors [MoA], Cytochrome P450 2C9 Inhibitors [MoA], Kinase Inhibitor [EPC], Multidrug and Toxin Extrusion Transporter 1 Inhibitors [MoA], Multidrug and Toxin Extrusion Transporter 2 K Inhibitors [MoA], P-Glycoprotein Inhibitors [MoA], Tyrosine Kinase Inhibitors [MoA]	N/A

Showing 1 to 5 of 5 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Ownership Information

Aventis Inc.
100 Morris Street
Morristown, NJ 07960
Phone: 908-981-5000
Website: https://www.sanofi.com/en

Company Information

Blueprint Medicines Corporation
45 Sidney Street
Cambridge, MA 02139
Phone: 617.374.7580
Website: www.blueprintmedicines.com
E-mail: info@blueprintmedicines.com

FEIN: 26-3632015
State of Formation: DE
Date Incorporated: 10/14/2008
DUNS#: 021905363

Leadership Team

Brittany Carroll, Head of Blueprint Medicines, a Sanofi Company
Business Address: 45 Sidney Street, Cambridge, MA 02139
Business Phone: 617-714-6673

Lauren Barnes, Head of Global Commercial
Business Address: 45 Sidney Street, Cambridge, MA 02139
Business Phone: 617-714-6673

Ariel Hurley, Head of Finance
Business Address: 45 Sidney Street, Cambridge, MA 02139
Business Phone: 617-714-6673

Jennifer Loebach, Head of Legal and Compliance
Business Address: 45 Sidney Street, Cambridge, MA 02139
Business Phone: 617-714-6673

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100 Morris Street
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Business Phone: 617-714-6673

Jennifer Loebach, Head of Legal and Compliance
Business Address: 45 Sidney Street, Cambridge, MA 02139
Business Phone: 617-714-6673

Designated Representative (not an officer)

Paul Skerker, Vice President, Head of Supply Chain
Business Address: 45 Sidney Street, Cambridge, MA 02139
Business Phone: 617-714-6673
Business Email: info@blueprintmedicines.com

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BLUEPRINT MEDICINES CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-EIGHTH DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4611605 8300

SR# 20251280443

Authentication: 203296613

Date: 03-28-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

BLUEPRINT MEDICINES CORPORATION
45 SIDNEY STREET
CAMBRIDGE, MA 02139

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: MA0000187

Type: Virtual Manufacturer

Issue Date: 01/05/2026

Expiration Date: 01/30/2027

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

0909

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 9485568

Application/License No. _____

BLUEPRINT MEDICINES, A SANOFI COMPANY (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 45 Sidney Street Cambridge, MA 02139 (Address of Applicant/Principal), as PRINCIPAL, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1299 Zurich Way, 5th Floor Schaumburg, IL 60196-1056 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on December 1, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of November, 20 25.

APPLICANT/PRINCIPAL
BLUEPRINT MEDICINES, A SANOFI COMPANY

Authorized Representative

SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

Surety Company's Representative

Wayne G. McVaugh, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Sara Owens

Witness Lori Shelton

Countersigned by:

Nevada Resident Agent Wayne G. McVaugh

Posted February 20, 2020

ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND
POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by Robert D. Murray, Vice President, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and **appoint** AnnMarie BREENE, Joanne C. WAGNER, Patricia DORSANEO, Cathy H. HO, Patricia A. RAMBO, Sara OWENS, Kimberly G. SHERROD, Patrick R. BREENE, Babette WARD, Dana DONAHUE, Lori S. SHELTON, Wayne G. MCVAUGH of Philadelphia, Pennsylvania, its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND**, this 25th day of February A.D. 2025.

ATTEST:
ZURICH AMERICAN INSURANCE COMPANY
COLONIAL AMERICAN CASUALTY AND SURETY COMPANY
FIDELITY AND DEPOSIT COMPANY OF MARYLAND

SEAL SEAL SEAL

By: Thomas O. McClennan
Vice President

By: Dawn E. Brown
Secretary

State of Maryland
County of Baltimore

On this 25th day of February, A.D. 2025 before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Thomas O. McClellan, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Genevieve M. Mason
Notary Public
My Commission Expire January 27, 2029

Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790

EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8. Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify of revoke any such appointment or authority at any time."

CERTIFICATE

I, the undersigned, Vice President of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 26th day of November, 2025.



MJ Pethick

Mary Jean Pethick
Vice President

TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
reportsfclaims@zurichna.com
800-626-4577

Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790

Scott Kipper, Commissioner of Insurance

Non-Resident Producer

Casualty, Property

WAYNE G MCVAUGH

100 N 18TH ST FL 16
PHILADELPHIA, PA 19103-2707

is authorized to transact business as described above

License No: 500206 Issue Date: 08-15-2006 Expiration Date: 08-31-2027

Generated by Sircon 322708223

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

WAYNE G MCVAUGH
100 N 18TH ST FL 16, PHILADELPHIA, PA 19103-2707

LICENSE NUMBER: 500206

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer
Casualty, Property

Issue Date: 08-15-2006 Expiration Date: 08-31-2027

Generated by Sircon 322708223

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Blueprint Medicines Corporation

Pharmacy/Wholesaler License # (if applicable) WH02656

Physical Address 45 Sidney Street

City Cambridge State MA Zip 02139

Mailing Address (if different from physical address)

City 45 Sidney Street State Massachusetts Zip 02139

Telephone (617) 374-7580 Website https://www.blueprintmedicines.com/

Licensing Company Email info@blueprintmedicines.com

Section 2: Personal Information

First Paul Middle Steven Last Skerker

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 45 Sidney Street

City Cambridge State Massachuse Zip 02139

Telephone [redacted] Email pskerker@blueprintmedicines.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cornell University			
Address	**City**	**State**	**Zip**
313 Campus Rd	Ithaca	NY	14850
Diploma/Degree obtained, if any			
Ph.D., Chemical Engineering			
School Name		**From - To (MM/YY – MM/YY)**	
Worcester Polytechnic Institute		09/83-06/89	
Address	**City**	**State**	**Zip**
100 Institute Rd	Worcester	MA	01609
Diploma/Degree obtained, if any			
B.S., Chemical Engineering			
School Name		**From - To (MM/YY – MM/YY)**	
Classical High School		09/75-06/79	
Address	**City**	**State**	**Zip**
1200 Massachusetts Avenue	Springfield	MA	01100
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/98-Present	[redacted]	Lexington	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Blueprint Medicines Corporation			09/23-Present	
Business Address		City	State	Zip
45 Sidney St.		Cambridge	MA	02139
Phone	Title		Number of Employed Hours	
617-374-7580	Vice President, Head of Global Supply Chain		40	
Description of Duties				
See attached Resume.				

Business Name			From - To (MM/YY – MM/YY)	
Foghorn Therapeutics			03/22-09/23	
Business Address		City	State	Zip
500 Technology Square, Suite 700		Cambridge	MA	02139
Phone	Title		Number of Employed Hours	
617-586-3100	Senior Director, Clinical Supply Chain		40	
Description of Duties				
See attached Resume.				

Business Name			From - To (MM/YY – MM/YY)	
Ipsen Bioscience			01/16-12/21	
Business Address		City	State	Zip
One Main Street		Cambridge	MA	02142
Phone	Title		Number of Employed Hours	
617-679-8500	Senior Director, Supply Chain, Onivyde		40	
Description of Duties				
See attached Resume.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

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Paul S. Skerker, Ph.D.

[redacted]

PROFESSIONAL EXPERIENCE:
Clinical and Commercial supply lead with experience building & leading groups, managing external CMOs, and leading the development of new assets from early stage through commercial launch.

2023– Present Blueprint Medicines, (45 Sidney St., Cambridge, MA, 02139, 617-374-7580)

Vice President, Head of Global Supply Chain
Responsible for leading clinical and commercial supply chain

- Lead groups responsible of clinical supply planning and logistics, commercial planning, commercial operations, logistics, supplier oversight, and international supply management
- Ensure effective supply of commercial and clinical drugs for patients
- Manage resources and budgets
- Align with other functional areas including commercial, regulatory, finance, technical operations, and quality.

Senior Director, Supply Chain
Responsible for leading clinical and commercial supply chain planning, logistics, and manufacturing

- Led project to identify and bring on line commercial supply planning tool
- Responsible for leading commercial supply planning organization including raw materials, API, DP, and FG including responsibility for managing key external suppliers.
- Responsible for leading organization responsible for all shipments of API and DP for both commercial and clinical programs
- Responsible for leading clinical supply organization including planning, packaging, and support for clinical supplies for all on-going clinical studies

2022– 2023 Foghorn Therapeutics, (500 Technology Square, Suite 700, Cambridge, MA, 02139, 617-586-3100)

Senior Director, Clinical Supply Chain
Responsible for leading clinical supply chain

- Develop process and manage forecasts for all clinical assets including DS, DP, and FG requirements
- Manage packaging and distribution vendor to ensure material is available for on-going studies
- Interact with clinical, clinical operations, and regulatory to align on short/long term plans

2016 – 2021 Ipsen Bioscience, (One Main Street, Cambridge, MA, 02142, USA, 617-679-8500)

Senior Director, Supply Chain, Onivyde
Responsible for managing commercial and clinical end to end supply chain for Onivyde, a nanoliposome product for treating patients with Pancreatic cancer.

- Managed resources directly responsible for supply/material planning, warehouse operations, external fill/finish and label/package vendors, serialization, and clinical supply.
- Directly responsible for developing S&OP process and managing forecasts / production plans utilizing make to order for global partners and make to stock for internal use covering API, DP, and FG manufacturing.

- Member of site management team; Active member of SAP site installation team.

Relationship Manager, External Manufacturing Organization, Palovarotene
Co-lead for CMC / Tech Ops responsible for validation and launch of ultra-rare disease asset

- Responsible for developing supply forecast plans, managing vendors, aligning internal resources across functions including pharmaceutical development, tech ops, global supply chain, and logistics.
- Managed overall validation schedule across DS, DP, and FG vendors to ensure alignment with regulatory requirements and launch plans
- Developed FG packaging options including blistering and CR packaging to support global markets

Director, Commercial and Clinical Supply Planning (Merrimack Pharmaceuticals, key assets purchased by Ipsen Bioscience in 2017)
Led groups responsible for managing commercial and clinical supply planning, management of all supply activities for clinical studies, determination of internal and external manufacturing of API, DP, and FG for commercial and clinical supply vendors

- Managed external vendors responsible for material manufacturing
- Rolled out S&OP process and developed internal/external manufacturing schedules to support commercial and clinical portfolio
- Responsible for managing starting materials inventory for internal manufacturing
- Built clinical supply organization to support all aspects of material requirements for phase 1-3 clinical programs

2014 – 2015 Cubist Pharmaceuticals, Lexington, MA, USA (Purchased by Merck in 2015)
Senior Director, Global Clinical Trial Supply
Manage group responsible for driving the execution of clinical trial supply strategies and oversight for all Investigational Product (IP) related functional and cross-functional deliverables in the planning and execution of clinical trials.

- Led preparation and interactions around all topics related to clinical supplies for EMA GCP product inspection.
- Managed the execution of IP planning, packaging, labeling, and distribution to ensure robust and secure end-to-end IP supply.
- Developed clinical supplies group including organization, processes, SOPs, interactions, and vendor management.
- Brought on line planning tools to ensure improved short and long term forecasts.
- Led effort to transition all clinical supplies management for Cubist programs to Merck post buy-out

1998- 2014 Takeda Pharmaceuticals (formerly Millennium Pharmaceuticals), Cambridge, MA, USA
Senior Director, Investigational Supply Operations, Pharmaceutical Sciences
Managed group responsible for forecasting clinical supplies, labeling and packaging of finished goods, and distribution of CTM to clinical sites.

- Organized and led team to develop comprehensive planning process and tools for clinical operations, clinical supplies, project management, and CMC to ensure alignment on development plans and supply requirements
- Built and led clinical supply teams managing 5 phase III and multiple phase I/II programs
- Evaluated and updated comparator purchasing processes and vendors to optimize (reduce) spend across phase III programs
- Developed technology/systems to improve handling of pooled supplies in IRT

- CMC lead for phase II Oncology asset
- Developed concept and led vendor effort to create system for capturing and tracking supply requirements for API, DP, and FG

Director, Investigational Supply Operations, Pharmaceutical Sciences
Managed group responsible for forecasting clinical supplies, labeling and packaging of finished goods, and distribution of CTM to clinical sites.

- Developed forecasting tool in collaboration with IRT vendor to enable detailed forecasts of complex clinical studies/programs utilizing Monte Carlo simulations
- Managed group responsible for supporting 10 development candidates.
- Developed processes for allowing for pooled CTM enabling cost savings and reduced logistics for global phase III and early stage programs

Senior Engineer II, Process Engineering, Pharmaceutical Sciences
Organized processes and vendors for the supply of API, starting materials and intermediates for small molecule synthesis of development compounds.

- Set-up and managed network of vendors for supply of starting materials and intermediates to support small molecule compounds in clinical development
- Managed vendors responsible for production of Phase II API

Director, Lead Discovery & Lead Discovery Technologies
Managed activities of High Throughput Biology, Drug Source, Automation and Data Management groups responsible for developing enzyme and cell based assays, supporting HTS, Hit to Lead, and Lead Optimization activities.

- Established group to support data analysis and data capture throughout company for drug discovery programs.
- Initiated and headed project to build company wide compound management and inventory system.
- Re-built compound handling including incorporation of new processes, automation, and IT support systems to handle greater than 1MM compounds.

EDUCATION:

Ph.D. School of Chemical Engineering, Cornell University, Ithaca, N.Y.
The Application of EPR Spectroscopy in the Study of Soluble and Immobilized Horse Liver Alcohol Dehydrogenase.

B.S., Chemical Engineering, Worcester Polytechnic Institute, Worcester, MA.

HONORS & HONOR SOCIETIES:

Tau Beta Pi, Phi Lambda Upsilon, Fred Hoffman Rhodes Fellow, Exxon Education Foundation Fellow

REFERENCES / PUBLICATIONS / PRESENTATIONS :

Available upon request

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Paul Sheldon
Original Signature (electronic, copies or stamps not accepted)

13-NOV-2023
Date

I, Paul Skerker, **certify that as the designated representative for**

Blueprint Medicines Corporation,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PS I am at least 21 years of age;
3. PS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Paul Skerker

Print Name (First, Last)

Paul Skerker

Original Signature (electronic, copies or stamps not accepted)

18-Nov-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Skerker

Print Name (First, Last)

Paul Skerker — 12/9/2025

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Middlesex

I, Paul Skerker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Paul Skerker — 12/09/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 9 day of December.

Notary Public Signature

Jodie Casleton
My Commission Expires July 14, 2028
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS

Blueprint Employee List

Preferred Name	First Name	Last Name
Paul	Paul	Akhenblit
Faris	Faris	Albayya
Calvin	Calvin	Allen
Francesc	Francesc	Almirall Alzamora
Rachel	Rachel	Ambroziak
Izzy	Isabel	Anacleto
Anand	Anand	Ananthakrishnan
Blanca	Blanca	Andres Fernandez
Amy	Amy	Andrews
Ed	Edison	Aniag
Wendy	Wendy	Ankrom
Daniele	Daniele	Antenucci
Alan	Alan	Armstrong
Sophia	Sophia	AuDuong
Katie	Kathryn	Ayres
Bobby	Robert	Baglione
Sandra	Sandra	Bai
Madison	Madison	Bailey
Melissa	Melissa	Bailey
James	James	Baker
Sabrina	Sabrina	Ballet
Tanja	Tanja	Balzano
Kankana	Kankana	Bardhan
Ben	Benjamin	Barlock
Lauren	Lauren	Barnes
Mariona	Mariona	Bartroli
Giacomo	Giacomo	Baruchello
Kevin	Kevin	Barvian
Renvye	Renvye	Battle
Molly	Molly	Bautista
Izzy	Isabelle	Beagen
Bethany	Bethany	Bearden
Clarisse	Clarisse	Benharoche
Seth	Seth	Bensussen
Duncan	Frederick	Berkeley
Vishwa	Vishwa	Bhavsar
Vinod	Vinod	Bhosale
Ilda	Ilda	Bidollari
Todd	Todd	Billet
Berit	Berit	Biniass
Andrea	Andrea	Biondo
Jason	Jason	Birri
Nivedita	Nivedita	Bisht

Samantha	Samantha	Blumsack
Heather	Heather	Bogard
Katie	Kathryn	Boino
Markus	Markus	Bollwein
Monica	Monica	Bonetti
Silvia	Silvia	Bonvicini
Andrew	Andrew	Boone
Christian	Christian	Borrelli
Pedro	Pedro	Bosch Mendoza
Melissa	Melissa	Bosquez
Madalina	Madalina	Botoroaga
Todd	Todd	Boudreau
Delphine	Delphine	Bourdon
Leigh	Leigh	Boutilier
Aaron	Aaron	Bowles
Neil	Neil	Brahmbhatt
Martina	Martina	Breitstadt
Tasha	Tasha	Brennan
Kristin	Kristin	Britton
Amanda	Amanda	Broderick
Carla	Carla	Brooks
Melissa	Melissa	Brooks
Mike	Michael	Brooks
Jenn	Jennifer	Brown
Jason	Jason	Brubaker
Elizabeth	Elizabeth	Burke
Kristin	Kristin	Butler
Paolino	Paolino	Cacciatore
Phil	Phillip	Calabretta
Tammy	Tammy	Campbell
Corey	Corey	Cannata
Mark	Mark	Capece
JB	Jarel	Carling
Courtney	Courtney	Carroll
Brittany	Brittany	Carroll
Antonio	Antonio	Casalucci
Liz	Elizabeth	Cashman
Andrea	Andrea	Casiraghi
Jodie	Jodie	Casleton
Kevin	Kevin	Caze
Elaine	Elaine	Ceniza
Felicia	Felicia	Chancy
Ranjith	Ranjith	Chandrasekar
An-Yun	An-Yun	Chang
Josh	Joshua	Chapman
Tayhlour	Tayhlour	Charlton
Dom	Oudom	Chea
Gary	Gary	Chedekel

Kevin	Kevin	Chen
Leslie	Leslie	Chen
Maxine	Maxine	Chen
Jun	Jun	Chen
Howard	Tzehaw	Chen
Min	Min	Chen
Alexandra	Alexandra	Cheng
Adam	Adam	Chin
Winston	Winston	Chow
Tat	Tat	Chu
Sean	Sean	Cirii
Meghan	Meghan	Clark
Sarah	Sarah	Clifford
Josh	Joshua	Close
Anna	Anna	Colabianchi
Clay	Hume	Coleman
Maureen	Maureen	Connelly
Deb	Deborah	Conrady
Chiara	Chiara	Conti
Derik	Derik	Cooley-Downs
Elliot	Elliot	Cooper
Casaundra	Casaundra	Copeland
Agnieszka	Agnieszka	Corsten
Cristina	Cristina	Cossetti
Emma	Emma	Cote
Christopher	Christophe	Coukos
Wes	Wesley	Cox-Muranami
Jonathan	Jonathan	Cramer
Kelly	Kelly	Cronan
Zach	Zachary	Crouch
Charlie	Charles	Daddona
Mark	Mark	Dahlin
Eric	Carl	Dahlquist
Yinghui	Yinghui	Dai
Nick	Nicholas	Daigle
Jana	Jana	Dailey
Fereidoon	Fereidoon	Daryaee
Mary Frances	Mary Franc	Davidson
Nicholas	Nicholas	Davis
Chevone	Chevone	Davis-Raglan
Omar	Omar	De Paolis
Sophie	Sophia	Debler
Lindbergh	Lindbergh	Dee
Shannon	Shannon	Delgado
Tessa	Tessa	DeLucia
Matthew	Matthew	DeMelo
Cheryl	Cheryl	DeMilo
Fabienne	Fabienne	Denhez

Heaven	Heaven	Denyer Wehrli
David	David	Deon
Emily	Emily	Dertz
Marissa	Marissa	Devlin
Mrudula	Mrudula	Dhavala
Himani	Himani	Dholakiya
Michelle	Michelle	Dialoiso
Sasa	Sasa	Dimitrijevic
Tom	Thomas	Dineen
Jeff	Zhihu	Ding
Doreen	Doreen	Do
Ali	Alison	Doane
Ashley	Ashley	Donna
Sona	Sona	Doshi
Michelle	Michelle	Dowda
Ashley	Ashley	Doyle
Larry	Lawrence	Drew
Terry	Terry	Driver
Andrea	Andrea	Dropkin-Mackey
Tracy	Yi	Du
Guangyan	Guangyan	Du
Tejas	Tejas	Dumaswala
Michelle	Michelle	Dunmore
Baptiste	Baptiste	Dupuy
Mike	Michael	Durkin
Jenkaa	Jenkaa	Dzekashu
Yvette	Yvette	Echevarria
Michelle	Michelle	Eddlemon
Maria Helene	Maria Heler	Edel
Alex	Alexandra	Elenis
Andrea	Andrea	Enking
Meredith	Meredith	Eno
Jaclyn	Jaclyn	Epstein
Rachel	Rachel	Erbach
Emily	Emily	Erickson
Lindsey	Lindsey	Erwin
Manolo	Manuel	Escudero
Guillaume	Guillaume	Esposito
Bianca	Bianca	Esposito
Santina	Santina	Estrada
Haley	Mary	Evans
Kerrie	Kerrie	Faia
Sejal	Sejal	Faldu
Eric	Eric	Faust
Hannah	Hannah	Favilla
Jens	Jens	Feierler
Jennifer	Jennifer	Ferraro
Ben	Benjamen	Filas

Elissa	Elissa	Findling
Claude	Claude	Fiset
Yvonna	Yvonna	Fisher-Jeffes
Karl	Karl	Fitt
Sarah	Sarah	Fitzpatrick
Sean	Sean	Flanagan
Brian	Brian	Floyd
Bill	William	Flugrad
Lily	Lilia	Flynn
Ben	Benjamin	Focht
Megan	Megan	Foley
Justin	Justin	Fossbender
Shemika	Shemika	Foxworth
Xavier	Francesc	Fradera Llinas
Mike	Michael	Franceschelli
Brenda	Brenda	Frank
David	David	Gan
Yong	Yong	Gao
Jorge	Jorge	Garcia-Lago
Eglys	Eglys	Garrido Noa
Andrea	Andrea	Gasperino
Max	Maxwell	Gbormittah
Jennie	Jie	Ge
Emilios	Emilios	Gemenetzidis
Ronalda	Ronalda	Germain
Peter	Peter	Gerstmayr
Felicia	Felicia	Gherghel
Kyrk	Kyriakos	Giannopoulos
Kelly	Kelly	Gifford
Faith	Faith	Gilbert
Amy	Amy	Gilooly
Betel	Betel	Girmay
Jennifer	Jennifer	Goddard
Tyler	Frank	Goldbaum
Lyndsay	Lyndsay	Golden
Phaneendhar	Phaneendh	Gondesi
Traci	Traci	Gonzales
Brandon	Brandon	Goodman
Troy	Troy	Goodman
Uschi	Ursula	Goody
Zach	Zachary	Gorman
Russ	Russell	Graceffa
Erin	Erin	Graeter
Alexandra	Alexandra	Grassian
Myke	Michael	Green
Teresa	Teresa	Green
Igor	Igor	Gridnev
Nick	Edward	Griffin

Bo	William	Grmoljez
Brian	Brian	Groendyke
Christina	Christina	Guggenberger
Craig	Craig	Gugger
Lee	Lee	Guidetti
Jian	Jian	Guo
Wendy	Wendy	Gustafson
Michaela	Michaela	Haeger
Andrew	Andrew	Haidle
Melanie	Melanie	Halbleib
Kari	Kari	Hamilton
Shannan	Shannan	Harris
Shuree	Shuree	Harrison
Russell	Russell	Hart
Deb	Deborah	Hartman
Kara	Kara	Haselton
Brian	Brian	Hastings
Sonny	Sonny	Hastings
Megan	Megan	Hatlen
Kelly	Kelly	Haugh
Kevin	Yifeng	He
Elina	Elina	Heese
Jared	Jared	Helfer
Torsten	Torsten	Herbertz
Anette	Anette	Hermani
Marcel	Marcel	Herold
John	John	Hess
Cammy	Camcat	Hill
Linh	Linh	Ho
Karen	Karen	Ho
Katherine	Katherine	Hocking
James	James	Hoenstine
Bryan	Bryan	Hogue
Tracy	Tracy	Holloway
Samantha	Samantha	Holmes
Will	William	Holt
Ethel	Ethel	Holtzclaw
Janet	Janet	Hong
Bill	William	Horchar
Nealia	Nealia	House
John	Chang-tai	Hsieh
Wei	Wei	Hu
Sandy	Sandra	Hudson
Travis	Travis	Hughes
Teresa	Teresa	Hurlbut
Ariel	Ariel	Hurley
Lucia	Lucia	Hwang
Maria	Maria	Iliou

Joshua	Joshua	Infantine
David	David	Ingalls
Whitney	Whitney	Inkrott
Oktay	Oktay	Ismet
Leni	Leni	Jacob
Rohitash	Rohitash	Jamwal
Pat	Patrick	Jarvis
Shachenika	Shachenika	Jean
Ashley	Ashley	Jewett Rodgers
Maria	Maria	Jimenez
Seunghee	Seunghee	Jo
John	John	Johans
Jennifer	Jennifer	Johnson
Tim	Timothy	Johnson
Jacqueline	Jacqueline	Jones
Michael	Michael	Jones
Tim	Timothy	Jones
Reinaldo	Reinaldo	Jones
Melissa	Melissa	Juenger
Angela	Angela	Juniphant
Jeanette	Jeanette	Kabia
Matt	Matthew	Kahn
Rahul	Rahul	Kalathiya
Mihika	Mihika	Kapai
Silva	Silva	Karasik
Goss	Goss	Kauffman
Kevin	Kevin	Keane
Jessica	Jessica	Kearney
Ken	Kenneth	Kearney
Jeff	Jeffrey	Keats
Hunter	Hunter	Kersey
Neal	Neal	Kharawala
Julie	Julie	Kilcoyne
Joe	Joseph	Kim
John	John	Kim
Amber	Amber	King
Caitlin	Caitlin	Kinkema
Jeremy	Jeremy	Knopp
Laura	Laura	Knopp
Gramoz	Gramoz	Kondakci
Parimal	Parimal	Korgaonkar
Robin	Robinkuma	Kothari
Roopa	Roopa	Kotian
Emma	Emma	Krolicki
Vladimir	Vladimir	Kubatin
Jean	Hsiang-Jea	Kung
Dennis	Dennis	Kwakye Darkwa
Caroline	Caroline	Labe

Tim	Timothy	LaBranche
Ben	Benjamin	Lampson
Mike	Michael	Landsittel
Joyce	Joyce	Lau
Nancy	Nancy	Lavin-Richard
Andrew	Andrew	Law
Kelly	Kelly	Le
Christopher	Christophe	Lee
Elaine	Elaine	Lee
Stephanie	Stephanie	Lee
Yujin	Yujin	Lee
Ivan	Ivan	Lee
Michael	Michael	Lee
Christopher	Christophe	Legacy
Dean	Dean	Legg
Stephanie	Stephanie	Leiva
Christophe	Christophe	Lemetre
Natalie	Natalie	Lett
Mikaela	Mikaela	Levine
Ronald	Ronald	Li
Hui	Hui	Li
Stella	Yunxing	Li
Chia-Cheng	Chia-Cheng	Li
Mark	Mark	Lightner
Paul	Paul	Lim
Hui-Min	Hui-Min	Lin
Michael	Michael	Linse
Xiang	Xiang	Liu
Sharon	Sharon	Lively
Nydia	Nydia	Llanes
Joyce	Joyce	Lo
Esty	Esty	Lobovits
Jennifer	Jennifer	Loebach
Ann	Ann	Loftus
Jackie	Jacquelin	Long
Meidy	Meidy	Lontoh
Karla	Karla	Lopez
Rocio	Rocío	López Marcos
Cristina	Cristina	Lopez-Barton
Ning	Ning	Lu
Susan	Susan	Lucas
Maggie	Xinyue	Ma
Mindy	Mindy	MacKenzie
Justin	Justin	Maderer
Shira	Shira	Magram
Trizia	Trizia	Mallari
Gemma	Gemma	Mandell
Kristina	Kristina	Marcello

Kella	Kella	Marchione
Colleen	Colleen	Marshall
Michael	Michael	Martin
Micheal	Micheal	Martineau
Alba	Alba	Martinez Diaz
Astrid	Astrid	Martinez-Matias
Haleigh	Haleigh	Martino
Melissa	Melissa	Masse
Vicken	Vicken	Matiossian
Javier	Javier	Matos Troche
Sara	Sara	McCutcheon
Emma	Emma	McGee
Cindi	Cynthia	McLoughlin
Ricardo	Ricardo	Medina
Camila	Camila	Medrano-Trochez
Reto	Reto	Meier
Rob	Robert	Meissner
Vanessa	Vanessa	Mejia
Govind	Govind	Menon
Georg Pirmin	Georg Pirmi	Meyer
Cara	Cara	Michalik
Rore	Rore	Middleton
Marci	Marci	Might
Kerri	Kerri	Miller
Lorin	Lorin	Miller
David	David	Miller
Yves	Yves	Millet
Nieves	Nieves	Mingo Moreno
Marissa	Marissa	Mizga
Julie	Julie	Mohnke
Ludivine	Ludivine	Moine
MK	Mary Kathe	Monahan
Amy	Amy	Monpara
Ed	Eduardo	Montiel
Meghan	Meghan	Moore
Samantha	Samantha	Moran
Theresa	Theresa	Moran
Lucas	Lucas	Morin
John	John	Morrison
Rosa	Rosa	Moscat
Kritika	Kritika	Mukherjee
Scott	Michael	Mulholland
Jessica	Jessica	Mullan
Preethi	Preethi	Munivenkata Swamy
Adriana	Adriana	Munoz
Javier	Javier I.	Munoz-Gonzalez
Marta	Marta	Murcia
Curran	Curran	Murphy-Chickering

Kyler	Kyler	Murray
Sadiah	Sadiah	Mussarrat
Lakshmi	Lakshmi	Muthuswamy
Claudia	Claudia	Nabaie
Hima	Himateja	Nagabhyrava
Ravi	Raghavendı	Nandagiri
Nabila	Nabila	Nazir
Aaron	Aaron	Neaves
Cindy	Cindy	Nguyen
Nate	Nathan	Nguyen
Regina	Regina	Nizzoli
Lindsey	Lindsey	Noble
Marie	Marie	Noel
Jacqui	Jacquelyn	Nolet
Adam	Adam	Noyes
Sarah	Sarah	O'Brien
Jim	James	O'Bryan
Kristine	Kristine	Oczkowski
Ibrahim	Ibrahim	Omoyayi
Chimnonso	Chimnonso	Onuoha
Nick	Nicholas	Orlando
Daniel	Daniel	Otto
Joan	Joan	Padrnos-Heinz
Mercy	Mercedes	Padron
Lindsay	Lindsay	Palmer
Maunik	Maunik	Parikh
Suhasini	Suhasini	Parimi
Nikita	Nikita	Patel
Falgun	Falgun	Patel
Dhwani	Dhwanikum	Patel
Priya	Priya	Patel
Aniket	Aniket	Patel
Carol	Carol	Patterson
Hilary	Hilary	Patterson
Erin	Erin	Pavao
Sylvie	Sylvie	Pecqueur
Claudio	Claudio	Pelosi
Phone	Phone	Perera
Kevin	Kevin	Perez
Cristian	Cristian	Perez
Kevin	Kevin	Perkins
Emanuele	Emanuele	Perola
Alice	Alice	Pesce
Dean	Dean	Petree
Linda	Linda	Petrini
Sean	Sean	Pines
Christina	Christina	Piper
Vittoria	Maria-Vittoı	Pisano

Jaki	Jacqueline	Pitman
Ivan	Ivan	Pizzocchia
Rosemarie	Rosemarie	Plaud
Mariateresa	Mariateresa	Pocchiari
Andrea	Andrea	Polychrones
Olivier	Olivier	Ponet
Dakota	Dakota	Powell
Julia	Julia	Powers
Alex	Alexander	Prokopienko
Alverina	Alverina	Pydynkowski
Weining	Weining	Qiu
Charles	Charles	Quaratiello
Anna	Anna	Quinci
Liesje	Liesje	Quinto
Tammy	Tammy	Rabern
Kolja	Kolja	Radau
Corinne	Corinne	Rahal
Aleksandar	Aleksandar	Rajlic
Samit	Samitkuma	Rajmane
Venkat	Venkat	Ramakrishnan
Alex	Alex	Ramon
Philip	Philip	Ramsden
Ashley	Ashley	Rand
Vishal	Vishal	Rathod
Doreen	Doreen	Reckler
Mohan	Mohan	Reddy
TJ	Thomas	Rego
Mohamed	Mohamed	Rhazlaoui
Joana	Joana	Ribeiro Caetano Lopes
Scott	Scott	Ribich
Catherine	Catherine	Riccio
Fred	Fred	Richards
Chris	Christine	Richardson
Alyssa	Alyssa	Richardson
Jennifer	Jennifer	Ridge
Stefania	Stefania	Rinaldi
Matt	Matt	Ring
Mik	Mikael	Rinne
Ronda	Ronda	Rippley
Andy	Andy	Ritchey
Atria	Atria	Rittig-Kavyanifar
Aixa	Aixa	Rivera Torres
Barbara	Barbara	Robens
Kristie	Kristie	Robinson
Josh	Joshua	Robles
Marly	Marly	Roche
Maria	Maria	Roche
Robyn	Robyn	Roche

Claudia	Claudia	Rockel
Tina	Tina	Rodriguez
Sara	Sara	Rodriguez Fahy
Elisabeth	Elisabeth	Rogers
Darlene	Darlene	Romelus
Juan	Juan	Romero
Peter	Peter	Rose
Tayla	Tayla	Rose
Mark	Mark	Rosenzweig
Tyler	Tyler	Rouskin-Faust
Willem	Willem	Roux
Emily	Emily	Rozsahegyi
Ben	Benjamin	Ruprecht
Paige	Paige	Ryan
Benjamin	Benjamin	Sahacic
Lydie	Lydie	Saint-Martin
Kenneth	John-Kenne	Sake
Thiwanka	Thiwanka	Samarakoon Mudiyanselage
Stefan	Stefan	Samuelson
Meg	Megan	Sanchez
Elizabeth	Elizabeth	Sanchez
Jennifer	Jennifer	Sandidge
Melissa	Melissa	Sanfilippo
Oliver	Oliver	Santos
Jessica	Jessica	Sapiro
Eric	Eric	Sarno
Karina	Karina	Sawan
Priyanka	Priyanka	Sawant
Robyn	Robyn	Scherber
Felix	Hans Albert	Scheuplein
Sebastian	Sebastian	Schlisio
Karen	Karen	Schneider
Jeff	Jeffrey	Schnyer
Eileen	Eileen	Schott-Harborth
Fatima	Fatima	Scipione
Heather	Heather	Scott
Rizwana	Rizwana	Seeham
Daniel	Daniel	Shaheen
Helen	Helen	Shanahan
Chris	Christophe	Shea
Andrew	Andrew	Shearer
Elaine	Elaine	Shelly
Jessica	Jessica	Sherry
Jennifer	Jennifer	Shevlin
Hongliang	Hongliang	Shi
Jen	Jennifer	Shidler
Rod	Rod	Shima
Hazheen	Hazheen	Shirnekhi

Pablo	Pablo	Sierra Gonzalez
Lianna	Lianna	Sifferlen
Hedwig	Hedwig	Silies
Jeff	Jeffrey	Simpson
Becca	Rebecca	Sims
Melody	Melody	Sipp
Michael	Michael	Siracusa
Kylie	Kylie	Sjoblom
Paul	Paul	Skerker
Chris	Christophe	Sloan
Matt	Matthew	Smith
Tyra	Tyra	Smith
Lisa	Lisa	Smith
Kelly	Kelly	Smith
Katy	Katy	Soave
Adam	Adam	Sodano
Ryan	Ryan	Sooy
Kristen	Kristen	Southard
Susanne	Susanne	Spiessl
Meaghan	Meaghan	Spurling
Ulf	Ulf	Staginnus
Blake	Blake	Starr
Leonor	Leonor	Stephens
Andrea	Andrea	Stipe
Jill	Jill	Struyk
Ralph	Ralph	Suckert
Sheng	Sheng	Sun
Wioletta	Wioletta	Superczynska
Anitha	Anitha	Suram
Stephanie	Stephanie	Surma
Maria	Maria	Taddeo
Pallavi	Pallavi	Tadimeti
Dipika	Dipika Dha	Tahelyani
Sam	Samson	Tamulevich
Kjersten	Kjersten	Teeter
Murali	Muralidhar	Tellakat
Elvira	Elvira	Tellegen
Nathalie	Nathalie	Telmon
Biswash	Biswash	Thakuri
Rajesh	Rajesh	Thamatam
Andre	André	Thielcke
Lars	Lars	Thiele
Ethan	Ethan	Thomas
Stacy	Stacy	Thompson
Sueann	Sueann	Thompson
Jordan	Jordan	Tocher
Anne Karin	Anne Karin	Toelge
Andy	Antranig	Torosian

Luis	Luis	Torres
Vu	Vu	Tran
Tina	Tina	Tran
Eric	Eric	Trierweiler
Mark	Mark	Trone
Alysen	Mary	Troy
Bin	Bin	Tu
Ogechi	Ogechi	Ukaigwe
Burcin	Burçin	Ülgen
Mukesh	Mukesh	Vadhel
Shruthi	Shruthi	Vaidhyanathan
Christopher	Christophe	Valentino
Csani	Csanad	Varga
Richard	Richard	Vargas
Morgan	Morgan	Vazquez
Greg	Gregory	Veneziano
Stephanie	Stephanie	Ventura
Saranya	Saranya	Venugopal
Ying	Ying	Verdi
Laura	Laura	Vidal
Juan	Juan	Villa
Tamil	Tamil	Viswanathan
Antonia	Antonia	Vitalo
Bob	Robert	Vitu
David	David	Vives
Mary Ann	Mary Ann	Vu
Jing	Jing	Wang
Mike	Michael	Wasserman
Nicole	Nicole	Webb
Alex	Alex	Wei
Taylor	Taylor	Weis
Nicoll	Nicole	Weiss
Weifan	Weifan	Weng
Aneesah	Aneesah	Whiteside
LeKeisha	LeKeisha	Whitworth
Mariya	Mariya	Wilkinson
Natalie	Natalie	Wills
Doug	Douglas	Wilson
Keven	Keven	Winder
Allison	Allison	Witham
Jonathan	Jonathan	Wojtkowiak
Jeannelle	Jeannelle	Wolf
Janet	Janet	Wong
Rentian	Rentian	Wu
Leon	Leon	Xia
Emily	Emily	Xie
Shiva	Srinivasa Sl	Yadlapalli
Aimee	Aimee	Yager

Guang	Guang	Yang
Joyce	Zhaoxia	Yang
Nick	Nicholas	Yankauskas
Huilan	Huilan	Yao
Lisa	Lisa	Young
Bei	Bei	Yu
Xiao	Xiao	Yu
April	Liang	Yuan
Chris	Christopher	Yuen
Leyre	Leyre	Zabaleta
Lydia	Lydia	Zachariadou
Aaron	Armen	Zakharyan
Andrew	Andrew	Zapp
Julianne	Julianne	Zeff
Yadi	Yadi	Zeng
Hui	Hui	Zhang
Dean	Zhuo	Zhang
Yinong	Yinong	Zhang

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: B. BRAUN MEDICAL INC.

Physical Address: 1601 WALLACE DR., SUITE 150

City: CARROLLTON State: TX Zip: 75006

Mailing Address (if different from physical address): 3773 CORPORATE PKWY.

City: CENTER VALLEY State: PA Zip: 18034

Telephone: 484-240-8378 Website: WWW.BBRAUNUSA.COM

Name of Designated Representative (DR): JOSH BLEVINS

Licensing Company Email: _____ DR Email: JOSH.BLEVINS@BBRAUNUSA.COM

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: TEXAS

Parent Company (if any): B. BRAUN OF AMERICA INC.

Corporation/Organization Name: B. BRAUN MEDICAL INC.

Mailing Address: 824 TWELFTH AVE

City: BETHLEHEM State: PA Zip: 18018

Telephone: 610-691-5400 Email: SA_LICENSING@BBRAUNUSA.COM

Contact Person Name: GANNON HESSMILLER

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

B. BRAUN MEDICAL INC.

Facility Name

Donald V. Nymberg Jr.

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/18/2025

Date

Board Use Only	Date Received: 1/7/26	Amount: $1000 CK 0475055

National Drug Code Directory

Current through January 15, 2026

Records marked with (U): This information was removed from publication, because the record is uncertified.

You have searched Finished drug products

Search Results: *'0264'*

Back to Search Page () | **Search Again ()**

CSV | Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
5-HTP Phenolic	44911-0264-1	6 [hp_X]/mL	LIQUID	ORAL		Energique, Inc.	44911-0264	5-Hydroxytryptophan	OXITRIPTAN	HUMAN OTC DRUG
Acetaminophen	0264-4050-80	10 mg/mL	INJECTION	INTRAVENOUS	NDA204957	B. Braun Medical Inc.	0264-4050	Acetaminophen	ACETAMINOPHEN	HUMAN PRESCRIPTION DRUG
Acetaminophen	0264-4050-90	10 mg/mL	INJECTION	INTRAVENOUS	NDA204957	B. Braun Medical Inc.	0264-4050	Acetaminophen	ACETAMINOPHEN	HUMAN PRESCRIPTION DRUG
Acetaminophen	0264-4100-90	10 mg/mL	INJECTION	INTRAVENOUS	NDA204957	B. Braun Medical Inc.	0264-4100	Acetaminophen	ACETAMINOPHEN	HUMAN PRESCRIPTION DRUG
Acetaminophen 250 mg and Ibuprofen 125 mg	70264-040-12	250 mg/1, 125 mg/1	TABLET, FILM COATED	ORAL	M013	R J General Corporation	70264-040	Acetaminophen 250 mg and Ibuprofen 125 mg	ACETAMINOPHEN; IBUPROFEN	HUMAN OTC DRUG
Acetic Acid	0264-2304-00	.25 g/100mL	IRRIGANT	IRRIGATION	NDA018161	B. Braun Medical Inc.	0264-2304	Acetic Acid	ACETIC ACID	HUMAN PRESCRIPTION DRUG
Acetic Acid	0264-2304-10	.25 g/100mL	IRRIGANT	IRRIGATION	NDA018161	B. Braun Medical Inc.	0264-2304	Acetic Acid	ACETIC ACID	HUMAN PRESCRIPTION DRUG
Aleve	70264-011-01	220 mg/1	TABLET	ORAL	NDA020204	R J General Corporation	70264-011	NAPROXEN SODIUM	NAPROXEN SODIUM	HUMAN OTC DRUG
Alka-Seltzer Original	70264-014-01	1000 mg/1, 325 mg/1, 1916 mg/1	TABLET, EFFERVESCENT	ORAL	M013	R J General Corporation	70264-014	ANHYDROUS CITRIC ACID, ASPIRIN, and SODIUM BICARBONATE	ANHYDROUS CITRIC ACID; ASPIRIN; SODIUM BICARBONATE	HUMAN OTC DRUG
Alka-Seltzer Plus Severe Cold and Flu PowerFast Fizz	70264-016-01	250 mg/1, 2 mg/1, 10 mg/1, 5 mg/1	TABLET, EFFERVESCENT	ORAL	M012	R J General Corporation	70264-016	chlorpheniramine maleate, acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide	ACETAMINOPHEN; CHLORPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PHENYLEPHRINE HYDROCHLORIDE	HUMAN OTC DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
Balanced Salt	0264-1945-10	.48 mg/mL, .3 mg/mL, .75 mg/mL, 3.9 mg/mL, 6.4 mg/mL, 1.7 mg/mL	SOLUTION	IRRIGATION	ANDA091387	B. Braun Medical Inc.	0264-1945	Sodium Chloride, Potassium Chloride, Calcium Chloride, Magnesium Chloride, Sodium Acetate, and Sodium Citrate	CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE	HUMAN PRESCRIPTION DRUG
Bayer Genuine Aspirin	70264-013-01	325 mg/1	TABLET	ORAL	M013	R J General Corporation	70264-013	Aspirin	ASPIRIN	HUMAN OTC DRUG
Benadryl Allergy	70264-024-01	25 mg/1	TABLET, FILM COATED	ORAL	M012	R J General Corporation	70264-024	DIPHENHYDRAMINE HYDROCHLORIDE	DIPHENHYDRAMINE HYDROCHLORIDE	HUMAN OTC DRUG
Bupivacaine Hydrochloride with Dextrose	0264-9379-88	7.5 mg/mL	INJECTION	SUBARACHNOID	ANDA209087	B. Braun Medical Inc.	0264-9379	Bupivacaine Hydrochloride with Dextrose	BUPIVACAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Calcium Gluconate	0264-5600-52	98 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA216541	B. Braun Medical Inc.	0264-5600	Calcium Gluconate	CALCIUM GLUCONATE MONOHYDRATE	HUMAN PRESCRIPTION DRUG
Cefazolin Sodium	0264-3107-11	3 g/50mL	SOLUTION	INTRAVENOUS	NDA050779	B. Braun Medical Inc.	0264-3107	Cefazolin Sodium	CEFAZOLIN SODIUM	HUMAN PRESCRIPTION DRUG
Cefazolin Sodium	0264-3103-11	1 g/50mL	SOLUTION	INTRAVENOUS	NDA050779	B. Braun Medical Inc.	0264-3103	Cefazolin Sodium	CEFAZOLIN SODIUM	HUMAN PRESCRIPTION DRUG
Cefazolin Sodium	0264-3105-11	2 g/50mL	SOLUTION	INTRAVENOUS	NDA050779	B. Braun Medical Inc.	0264-3105	Cefazolin Sodium	CEFAZOLIN SODIUM	HUMAN PRESCRIPTION DRUG
CEFEPIME HYDROCHLORIDE AND DEXTROSE	0264-3193-11	1 g/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050821	B. Braun Medical Inc.	0264-3193	CEFEPIME HYDROCHLORIDE	CEFEPIME HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
CEFEPIME HYDROCHLORIDE AND DEXTROSE	0264-3195-11	2 g/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050821	B. Braun Medical Inc.	0264-3195	CEFEPIME HYDROCHLORIDE	CEFEPIME HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Cefoxitin and Dextrose	0264-3123-11	1 g/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA065214	B. Braun Medical Inc.	0264-3123	CEFOXITIN SODIUM	CEFOXITIN SODIUM	HUMAN PRESCRIPTION DRUG
Cefoxitin and Dextrose	0264-3125-11	2 g/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA065214	B. Braun Medical Inc.	0264-3125	CEFOXITIN SODIUM	CEFOXITIN SODIUM	HUMAN PRESCRIPTION DRUG
CEFTRIAXONE AND DEXTROSE	0264-3153-11	1 g/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050796	B. Braun Medical Inc.	0264-3153	CEFTRIAXONE	CEFTRIAXONE SODIUM	HUMAN PRESCRIPTION DRUG
CEFTRIAXONE AND DEXTROSE	0264-3155-11	2 g/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050796	B. Braun Medical Inc.	0264-3155	CEFTRIAXONE	CEFTRIAXONE SODIUM	HUMAN PRESCRIPTION DRUG
Cefuroxime and Dextrose	0264-3112-11	750 mg/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050780	B. Braun Medical Inc.	0264-3112	CEFUROXIME AND DEXTROSE	CEFUROXIME SODIUM	HUMAN PRESCRIPTION DRUG
Cefuroxime and Dextrose	0264-3114-11	1.5 g/50mL	INJECTION, SOLUTION	INTRAVENOUS	NDA050780	B. Braun Medical Inc.	0264-3114	CEFUROXIME AND DEXTROSE	CEFUROXIME SODIUM	HUMAN PRESCRIPTION DRUG
Chloroformum	37662-0264-1	500 [hp_C]/1	PELLET	ORAL		Hahnemann Laboratories, INC.	37662-0264	Chloroformum	CHLOROFORM	HUMAN OTC DRUG

Top Four Suppliers					
Name	**Street**	**City**	**Region**	**Postal**	**Country**
B. BRAUN AVITUM AG	Schwarzenberger Weg 73-79	Melsungen	6	34212	DE
B. BRAUN MELSUNGEN AG	Carl-Braun-Straße 1	Melsungen	6	34212	DE
B. BRAUN US DEVICE MANUFACTURING LLC	901 Marcon Blvd	Allentown	PA	18109	US
N/A					

B. Braun Medical Inc.

DIRECTORS:

Joseph J. Grispo, Jr.

OFFICERS:

Donald V. Nymberg Jr.

President

Angela R. Holloway-Kingston

Vice President

Jonathan R. Frisbie

Treasurer

Gannon A. Hessmiller

Corporate Secretary

B. Braun of America Inc

824 Twelfth Ave., Bethlehem, PA 18018

Sole Shareholder

From: SA_Licensing BBMUS_Service <SA_Licensing@bbraunusa.com>
Sent: Thursday, January 15, 2026 12:16 PM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: Re: Nevada Out-of-State Wholesaler Application-B. Braun Medical Inc.

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

1. B. Braun Medical Inc. holds the labeler code for their products. To clarify, no manufacturing takes place at this facility.

2. I accidentally attached the DE Certificate to this application. This facility is located in TX which does not provide a Certificate of Good Standing. I have attached a form from Texas Comptroller which I hope will satisfy your request.

Looking for a Certificate of Good Standing?

3

Although the comptroller's office no longer uses the term, "certificate of good standing" is sometimes used to refer to a certificate issued by the Texas Comptroller of Public Accounts regarding an entity's franchise tax account status. The comptroller's office now refers to these certificates as "certificates of account status." Information about certificates of account status is available from the comptroller. You may contact the comptroller at (800) 252-1381 for assistance as well.

. I have attached the update COI.

Please let me know if you require anything additional.

Thank you,

John Gauweiler – Licensing Specialist
B. Braun Medical Inc – 3773 Corporate Pkwy, Center Valley, PA 18034
484-240-8378
John.Gauweiler@bbraunusa.com
www.bbraunusa.com

FRANCHISE TAX ACCOUNT STATUS

This record as of January 15, 2026 at 14:58:24

B. BRAUN MEDICAL INC.

Texas Taxpayer Number:	12321167749
Mailing Address:	824 12TH AVE BETHLEHEM, PA 18018 - 3524
Right to Transact Business in Texas:	ACTIVE
State of Formation:	TX
SOS Registration Status (SOS status updated each business day):	ACTIVE
Effective SOS Registration Date:	04/16/2024
Texas SOS File Number:	0805507925
Registered Agent Name:	CORPORATION SERVICE COMPANY DBA CSC - LAWYERS INCO
Registered Office Street Address:	211 E. 7TH STREET, SUITE 620 AUSTIN, TX 78701

Public Information Report for Year 2025

Title	Name and Address
SEC	**GANNON HESSMILLER** 824 TWELFTH AVENUE BETHLEHEM, PA 18018 **Source:** CPA

DIRECTOR	**JOSEPH GRISPO JR** 824 TWELFTH AVENUE BETHLEHEM, PA 18018 **Source:** CPA

Information on this site is obtained from the most recent Public Information Report (PIR) submitted to the Comptroller of Public Accounts (CPA) or from the most recent PIR processed by the Secretary of State (SOS). Annual PIRs submitted to the CPA are forwarded to the SOS.

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/medical-device-manufacturers-distributors**.
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

B BRAUN MEDICAL INC
3773 CORPORATE PKWY
CENTER VALLEY PA 18034

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

B BRAUN MEDICAL INC

1601 WALLACE DR STE 150
CARROLLTON, TX 75006

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE DISTRIBUTOR

License # 1003815
Expires: September 3, 2027

NON-TRANSFERABLE

Commissioner

515748

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/07/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, LLC.
3031 N. Rocky Point Drive West, Suite 700
Tampa, FL 33607

CN101209282--ALL-25-26 Prod

CONTACT NAME: Marsh USA LLC
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):**
E-MAIL ADDRESS: Tampa.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : HDI Global Insurance Company	41343
INSURER C : Indemnity Ins Co Of North America	43575
INSURER D : Illinois Union Insurance Co	27960
INSURER E : ACE Fire Underwriters Insurance Company	20702
INSURER F :	

INSURED
B. Braun Medical, Inc
200 Boulder Drive
Breinigsville, PA 18031

COVERAGES **CERTIFICATE NUMBER:** ATL-006048205-10 **REVISION NUMBER:** 13

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			HDO G49375207	12/31/2025	12/31/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	5,000,000 1,000,000 10,000 5,000,000 10,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			ISA H11360749	12/31/2025	12/31/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	1,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			CUD1067118	01/01/2026	01/01/2027	EACH OCCURRENCE AGGREGATE	$ $	10,000,000 10,000,000
C E C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		WLR C72804387 (PA) SCF C72804399 (WI) WLR C72804375 (AOS)	12/31/2025 12/31/2025 12/31/2025	12/31/2026 12/31/2026 12/31/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
D	Products Liability (Claims Made)			G4744360A 003	01/01/2026	01/01/2027	Per Occurrence Aggregate		10,000,000 10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: Locations: 1341 N. Clyde Morris Blvd., Daytona Beach, FL 32117; 12400 Arrow Rte., Rancho Cucamonga, CA 91739; 1601 Wallace Dr., Suite 150 Carrollton, TX 75006

Umbrella Coverage provides coverage on a Claims Made Basis as respects the underlying Products Liability.

CERTIFICATE HOLDER

Prologis, Inc.
1800 Wazee Street Suite 500
Denver, CO 80202

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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SURETY RIDER

To be attached to and form a part of

Bond No. 019066373

dated effective October 10, 2018
(MONTH-DAY-YEAR)

executed by B. Braun Medical Inc. , as Principal,
(PRINCIPAL)

and by Liberty Mutual Insurance Company , as Surety,

in favor of State of Nevada and to the Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

The Principal address to:

1601 Wallace Dr. Suite 150, Carrollton, TX 75006

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective November 24, 2025
(MONTH-DAY-YEAR)

Signed and Sealed November 24, 2025
(MONTH-DAY-YEAR)

B. Braun Medical Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Liberty Mutual Insurance Company
(SURETY)

By: _____
TerryAnn Gonzales-Selman, Attorney-In-Fact

S-0443/GEEF 10/99

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint,

TerryAnn Gonzales-Selman

all of the city of New York, state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 24th day of November 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2024

Assets		Liabilities	
Cash and Bank Deposits	$4,608,826,756.00	Unearned Premiums	$9,890,896,878.00
*Bonds – U.S Government	$4,281,375,446.74	Reserve for Claims and Claims Expense	$29,467,071,865.00
*Other Bonds	$21,566,489,527.26	Funds Held Under Reinsurance Treaties	$341,948,172.00
*Stocks	$15,589,644,012.00	Reserve for Dividends to Policyholders	$954,025.00
Real Estate	$86,497,925.00	Additional Statutory Reserve	$150,547,865.00
Agents' Balances or Uncollected Premiums	$7,512,975,129.00	Reserve for Commissions, Taxes and Other Liabilities	$5,049,906,410.00
Accrued Interest and Rents	$225,249,712.00	**Total**	**$47,104,416,171.00**
Other Admitted Assets	$19,367,663,200.00	Special Surplus Funds	$174,153,086.00
Total Admitted Assets	**$74,539,483,661.00**	Capital Stock	$10,000,075.00
		Paid in Surplus	$13,209,595,772.00
		Unassigned Surplus	$13,415,980,561.00
		Surplus to Policyholders	$27,435,067,490.00
		Total Liabilities and Surplus	**$74,539,483,661.00**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2024, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2025.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: B. Braun Medical Inc. MDEG License # (if applicable): TBD

Physical Address: 1601 Wallace Dr., Suite 150

City: Carrollton State: TX Zip: 75006

Mailing Address (if different from physical address): 3773 Corporate Pkwy

City: Center Valley State: PA Zip: 18034

Telephone: 484-240-8378 Website: www.bbraunusa.com

Licensing Company Email: sa_licensing@bbraunusa.com

Section 2: Personal Information

First: Joshua Middle: Randall Last: Blevins

Alias(es, nicknames, name changes, etc.): Josh

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Providence Village State: TX Zip: [redacted]

Telephone: [redacted] Email: josh.blevins@bbraunusa.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fallston High School		09/2004 - 05/2008	
Address	**City**	**State**	**Zip**
2301 Carrs Mill Rd	Fallston	MD	21047
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2024 - Present	[redacted]	Providence Village	TX	[redacted]
07/2022 - 04/2024		Aubrey	TX	
06/2018 - 07/2022		Bunker Hill	WV	
06/2017 - 06/2018		Fallston	MD	
06/2015 - 06/2017		Waleska	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
B. Braun Medical Inc.			05/2022 - Present	
Business Address		**City**	**State**	**Zip**
1601 Wallace Dr., Suite 150		Carrollton	TX	75006
Phone	**Title**		**Number of Employed Hours**	
410-618-7405	Service Manager		8,000	
Description of Duties				
Oversee distribution, manufacturing, and service/repair of compounding systems.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/20/2025
Date

I, Joshua Randall Blevins, **certify that as the MDEG Administrator for**

B. Braun Medical Inc.,

that I (initial that you have read and meet the following requirements):

1. JRB Have a high school diploma or its equivalent;
2. JRB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JRB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JRB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joshua Blevins
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler B. BRAUN MEDICAL INC.

Pharmacy/Wholesaler License # (if applicable) TBD

Physical Address 1601 WALLACE DR., SUITE 150

City CARROLLTON State TX Zip 75006

Mailing Address (if different from physical address) 3773 CORPORATE PKWY

City CENTER VALLEY State PA Zip 18034

Telephone 484-240-8378 Website WWW.BBRAUNUSA.COM

Licensing Company Email SA_LICENSING@BBRAUNUSA.COM

Section 2: Personal Information

First JOSHUA Middle RANDALL Last BLEVINS

Alias(es, nicknames, name changes, etc.) JOSH

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City PROVIDENCE VILLAGE State TX Zi[redacted]

Telephone [redacted] Email JOSH.BLEVINS@BBRAUNUSA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
FALLSTON HIGH SCHOOL		09/2004 - 05/2008	
Address	**City**	**State**	**Zip**
2301 CARRS MILL RD	FALLSTON	MD	21047
Diploma/Degree obtained, if any			
HS DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2024 - PRESENT	[redacted]	PROVIDENCE VILLAGE	TX	[redacted]
07/2022 - 04/2024		AUBREY	TX	
06/2018 - 07/2022		BUNKER HILL	WV	
06/2017 - 06/2018		FALLSTON	MD	
06/2015 - 06/2017		WALESKA	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
B BRAUN MEDICAL INC.			05/2022 - PRESENT	
Business Address		**City**	**State**	**Zip**
1601 WALLACE DR. SUITE #150		CARROLLTON	TX	75006
Phone	**Title**		**Number of Employed Hours**	
410-618-7405	SERVICE MANAGER		8000	
Description of Duties				
OVERSEE DISTRIBUTION, MANUFACTURING AND SERVICE/REPAIRS OF COMPOUNDING SYSTEMS				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

11/11/2025

Date

I, JOSHUA RANDALL BLEVINS, **certify that as the designated representative for**

B BRAUN MEDICAL INC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JRB I am at least 21 years of age;
3. JRB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JRB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JRB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JRB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JRB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JOSHUA. BLEVINS

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

~~BLEVINS, JOSHUA~~ Joshua Blevins 11/11/2025

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Denton

I, Joshua Blevins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/11/2025

Date

Subscribed and Sworn to before me this 11th day of Nov 2025.

Notary Public Signature

CATHERINE MCLEOD
Notary Public, State of Texas
Comm. Expires 05-06-2029
Notary ID 135514370

(Seal)

Carrollton, TX - Employee List	
Last Name	**First Name**
Camarena	Jesus
Johnson	Dennis
Paulson	James
Blevins	Joshua
Navarro	Paul
Nduba	Anthony
Zuniga	Daisy
Borland	Franklin
Davis	Leeda
Rodriguez	Maria
Brown	Nell
Ergete	Bezunesh
Chhoeuy	Chan
Obed	Cyprian
Messelu	Haimanot
Lopez	Leonor
Khuu	Loi
Singthavong	Marvyn
Erickson	Matthew
Keo	Phan
Xanouvong	Phone
Beyene	Tesfay
Armenta	Vickie
Thoan	Charles
Casarez	Cynthia
Moore	Kaniece
Sath	Lam
Traynor	Marcellus
Quarshie	Martin
Boatright	Melissa
Pham	My
Jacobo	Rebecca
Intharack	Soutsada
Gasdik	Adam
Guerro	Brian
Nunn	Bruce
Villeneuve	Kimy
Lindahl	Michael
Sanchez-Armas	Omar
Wilson	Scott
Nunes	Sergio
Cisneros	Socorro
Fisher	Steve

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Ceva Animal Health, LLC

Physical Address: 8735 Rosehill Road , Suite 300

City: Lenexa State: KS Zip: 66215

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 913-894-0230 Website: www.ceva.us

Name of Designated Representative (DR): Alicia Henk

Licensing Company Email: regulatory.us@ceva.com DR Email: alicia.henk@ceva.com

Entities the Wholesaler will Serve (all applicable)	Products to be Handled or Wholesaled (all applicable)	Type of Wholesaling (all applicable)
☐ Pharmacies ☐ Practitioners ☐ Hospitals ■ Wholesalers ■ Veterinarians ☐ Others:	☐ Dangerous Drugs ☐ Controlled Substances ☐ *Medical devices, equipment, supplies, gases ■ Others: Veterinary prescription drugs Over the counter	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
			N/A	
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9-3-2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: DPT Laboratories, Ltd.
Address: 307 Josephine St City: San Antonio State: TX Zip: 78215
Name: Argenta US Manufacturing LLC
Address: 12707 Shawnee Mission Parkway City: Shawnee State: KS Zip: 66216
Name: Alcami Carolinas Corporation
Address: 4221 Faber Place Drive City: Charelston State: SC Zip: 29405
Name: Catalent Germany Schorndorf GmbH
Address: Steinbeisstrasse 1-2 City: Schorndorf D-73614 State: Zip: DEU

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Ceva US Holdings
Corporation/Organization Name: Ceva Animal Health, LLC
Mailing Address: 8735 Rosehill Road, Suite 300
City: Lenexa State: KS Zip: 66215
Telephone: 913-894-0230 Email: regulatory.us@ceva.com
Contact Person Name: Katy Hernandez

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an " " on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**				
• **List the top four corporation shareholders and their percent ownership.**				
• **List of all corporation shareholders and their percent ownership.**				
• **List of all partners and their percent ownership.**				
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**				
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/				
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/				
• **Copy of DEA certificate if handling controlled substances**				
• **Copy of current SEC 10K or 8K** (First 15 pages only)				
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**				
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**				
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/				
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).				
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.				
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.				

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Ceva Animal Health, LLC

Facility Name

Anthony Strait

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-3-2025

Date

Board Use Only	Date Received: 11117175	Amount: $1000 CK 663765

13744 labeler

Effective: 10/02/2025

Ceva Drug Products with NDC Numbers

- Cardalis® (spironolactone and benazepril hydrochloride chewable tablets) - Rx
  - 20 mg/2.5 mg - 30 ct - 13744-805-30
  - 20 mg/2.5 mg- 90 ct - 13744-805-90
  - 40 mg/5 mg - 30 ct - 13744-807-30
  - 40 mg/5 mg - 90 ct - 13744-807-90
  - 80 mg/10 mg - 30 ct - 13744-809-30
  - 80 mg/10 mg - 90 ct - 13744-809-90
- Doxidyl® (deracoxib) Chewable Tablets - Rx
  - 12 mg, 30 ct - 13744-530-01
  - 12 mg, 90 ct - 13744-530-02
  - 25 mg, 30 ct - 13744-531-01
  - 25 mg, 90 ct - 13744-531-02
  - 75 mg, 30 ct - 13744-532-01
  - 75 mg, 90 ct - 13744-532-01
  - 100 mg, 30 ct - 13744-533-01
  - 100 mg, 90 ct - 13744-533-02
- GleptoForte® (gleptoferron)200 mg/mL iron injection - OTC
  - 100 mL - 13744-525-01
  - 250 mL - 13744-525-02
- Kesium® (amoxicillin and clavulanate potassium tablets)- Rx
  - 62.5 mg - 13744-540-01
  - 125 mg - 13744-541-01
  - 250 mg - 13744-542-01
  - 375 mg - 13744-543-01
- Meloxidyl® (meloxicam oral suspension) 1.5 mg/mL - Rx
  - 10 mL - 13744-505-01
  - 32 mL - 13744-505-32
  - 100 mL - 13744-505-10
  - 200 mL - 13744-505-20
- MilbeGuard® (milbemycin oxime) Flavored Tablets - Rx
  - 2.3 mg - 13744-510-10
  - 5.75 mg - 13744-511-10
  - 11.5 mg - 13744-512-10
  - 23.0 mg - 13744-513-10
- Modulis® (cyclosporine oral solution) USP Modified 100mg/mL for Dogs - Rx
  - 15 mL - 13744-535-01
  - 30 mL - 13744-535-02
  - 50 mL - 13744-535-03
- Modulis® (cyclosporine oral solution) USP Modified 100mg/mL for Cats - Rx
  - 4.7 mL - 13744-536-01
  - 15 mL - 13744-536-02
- PANOQUELL®-CA1 (fuzapladib sodium for injection) 14mg per vial - Rx
  - 6 mL vial- 13744-812-01

FDA Rx Drug Products & CMO info

- Cardalis® (spironolactone and benazepril hydrochloride chewable tablets)
  - Catalent Germany Schorndorf GmbH
    - Steinbeisstrasse 1-2, Schorndorf D-73614, DEU
    - DUNS # 315732628
    - FEI # 3003831171
- Doxidyl® (deracoxib) Chewable Tablets
  - Pillar5 Pharma, Inc.
    - 365 Madawaska Blvd., Arnprior, Ontario K7S 0C9, CAN
    - DUNS # 243904344
    - FEI # 3000241849
- Meloxidyl® (meloxicam oral suspension) 1.5 mg/mL
  - DPT Laboratories, Ltd.
    - 307 Josephine St, San Antonio, TX 78215
    - DUNS # 832224526
    - FEI # 1628114
  - Argenta US Manufacturing LLC
    - 12707 Shawnee Mission Parkway, Shawnee, KS 66216
    - DUNS# 119402875
    - FEI# 1910953
- MilbeGuard® (milbemycin oxime) Flavored Tablets
  - Vetio Animal Health ULC
    - 9622 rte Transcanadienne, Saint-Laurent, Quebec H4S 1V9, CAN
    - DUNS # 243313714
    - FEI # 3005813881
- Modulis® For Dogs (cyclosporine oral solution) USP Modified 100 mg/mL
  - Catalent Germany Eberbach GmbH
    - Gammelsbacher Strasse 2, Eberbach, Baden 69412 Germany
    - DUNS# 318612223
    - FEI#: 3002808098
- Modulis® For Cats (cyclosporine oral solution) USP Modified 100 mg/mL
  - Catalent Germany Eberbach GmbH
    - Gammelsbacher Strasse 2, Eberbach, Baden 69412 Germany
    - DUNS# 318612223
    - FEI#: 3002808098
- PANOQUELL®-CA1 (fuzapladib sodium for injection)
  - Alcami Carolinas Corporation
    - 4221 Faber Place Drive, Charelston, SC 29405
    - DUNS # 832394733
    - FEI # 1000110990
- Kesium® (amoxicillin and clavulanate potassium tablets) for Dogs and Cats

- PenCef Pharma GmbH
  - Breitenbachstr. 13-14, Brandenburg D-13509 Germany
  - DUNS # 332702997
  - FEI # 3008654273

FDA OTC Drug Products & CMO info

- GleptoForte® (gleptoferron) Injection 200mg/mL of iron
  - União Química Farmacêutica Nacional SA
  - Av. PRESIDENTE TANCREDO DE ALMEIDA NEVES 1.555, Guarulhos, SP 07111-00, BRA
  - DUNS # 919987977
  - FEI # 3004063802

Ceva Animal Health , LLC

8735 Rosehill Road, Suite 300, Lenexa, KS 66215
FEIN: 20-4676881
Incorporated in the State of Delaware on 01/01/2011

Ceva US Holdings, Inc. – Parent Company

Address:	8735 Rosehill Road, Suite 300, Lenexa, KS 66215
FEIN:	98-0472605
Ownership:	100%

Incorporated in the State of Delaware on 5/16/2005

Brad McCollum– SVP North

America Ceva Animal Health

Business Address:	8735 Rosehill Road, Lenexa, KS 66215
Business Phone:	913-295-2215

Anthony Strait – Secretary

Business Address:	8735 Rosehill Road, Lenexa, KS 66215
Business Phone:	913-894-0230

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CEVA ANIMAL HEALTH, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF NOVEMBER, A.D. 2025.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 205241433

Date: 11-05-25

4135396 8300

SR# 20254472034

You may verify this certificate online at corp.delaware.gov/authver.shtml

NOTICE: Display this renewal with original certificate in a prominant location site

APPLICANT MAILING ADDRESS

CRAIG WALLACE
CEVA ANIMAL HEALTH, LLC
8735 ROSEHILL RD, STE. 300
LENEXA, KS 66215

Manufacturer Certificate of Renewal of Permit

Original Permit #	4-31224
Company Name	CEVA ANIMAL HEALTH, LLC
Schedules	
Address	8735 ROSEHILL RD, STE. 300
City/State/Zip	LENEXA, KS 66215
Owner	Ceva Animal Health LLC

KANSAS STATE BOARD OF PHARMACY

2025 - 2026

Expires June 30, 2026
(This is a renewal, not an original registration)

Executive Secretary
(785) 296-4056

RIDER

To be attached to and form part of:

Bond Number	83BSBGY3124
originally dated	December 10, 2014
issued by the	HARTFORD FIRE INSURANCE COMPANY
originally in the amount of	$ 100,000.00
originally on behalf of	CEVA ANIMAL HEALTH, LLC (Principal)
and in favor of	NEVADA STATE BOARD OF PHARMACY (Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

The SECOND LOCATION shall be added:

8735 Rosehill Road, Suite 300 Lenexa, KS 66215

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider is to be Effective this 30th day of December, 2025.

Signed, Sealed & Dated this 30th day of December, 2025.

CEVA ANIMAL HEALTH, LLC
(Principal)

By: _____

HARTFORD FIRE INSURANCE COMPANY
(Surety)

By: _____
Derek J. Elston, Attorney-in-Fact

DUPLICATE ORIGINAL

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBGY3124

Application/License No. _____

CEVA Animal Health, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8600 NE Underground Drive, Pillar 303 Kansas City, MO 64161 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 12/10/2014 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 10th day of December, 20 14.

APPLICANT/PRINCIPAL
CEVA Animal Health, LLC

Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness 11/7/2024

TRACEY BAILES
Notary Public, State of Kansas
My Appointment Expires 7-26-2026

SIGNED and SEALED in the presence of:

Witness Aaron Griffin

Witness Brea Jenkins

Countersigned by:
N/A
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-553702

- ☒ **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- ☒ **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- ☒ **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :
Derek J. Elston, Jennifer L. Jakaitis, Richard Casas, Aaron D. Griffin, Bartlomiej Siepierski, Aerie Walton of CHICAGO, Illinois

their true and lawful Attorney(s)-In-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of 12/30/2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2021

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

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Agency Code: 83-553702

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

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Maritza Arce
My Commission HH 287363
Expires July 13, 2026

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Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised July 31, 2024

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Ceva Animal Health, LLC
Pharmacy/Wholesaler License # (if applicable): Applying
Physical Address: 8735 Rosehill Road , Suite 300
City: Lenexa State: KS Zip: 66215
Mailing Address (if different from physical address): Same as above
City: State: Zip:
Telephone: 913-894-0230 Website: www.ceva.us
Licensing Company Email: regulatory.us@ceva.com

Section 2: Personal Information

First: Alicia Middle: Kay Last: Henk
Alias(es, nicknames, name changes, etc.): Alicia Kay Wren
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X
Mailing Address: 8735 Rosehill Road , Suite 300
City: Lenexa State: KS Zip: 66215
Telephone: 913-894-0230 Email: alicia.henk@ceva.com
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Diego State University		To 2009	
Address	**City**	**State**	**Zip**
online classes		Calif	
Diploma/Degree obtained, if any			
Regulatory Affairs Certification			
School Name		**From - To (MM/YY – MM/YY)**	
Univeristy of Missouri - Kansas City		To 1989	
Address	**City**	**State**	**Zip**
	Kansas City	MO	
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
University of Nebraska		To 1984	
Address	**City**	**State**	**Zip**
	Lincoln	NE	
Diploma/Degree obtained, if any			
BS Chemistry / Life Sciences			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
To current	[redacted]	Kansas City	MO	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Ceva Animal Health, LLC			01/2008 - Present	
Business Address		**City**	**State**	**Zip**
8735 Rosehill Road, Suite 300		Lenexa	KS	66215
Phone	**Title**		**Number of Employed Hours**	
913-894-0230	Director - Development & Regulatory		22,720	
Description of Duties				
Regulatory Affairs, Research and Development				

Business Name			From - To (MM/YY – MM/YY)	
Pfizer Animal Health			1985 - 2007	
Business Address		**City**	**State**	**Zip**
007 S, MO 291 HWY		Les Summit	MO	64081
Phone	**Title**		**Number of Employed Hours**	
816-525-2252	Sr. Manager - Tech Support		192,850	
Description of Duties				
Product & Process Development				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
			N/A	
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/21/2025
Date

I, Alicia Henk, **certify that as the designated representative for**

Ceva Animal Health, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AH I am at least 21 years of age;
3. AH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Alicia Henk

Print Name (First, Last)

Alicia K Henk

Original Signature (electronic, copies or stamps not accepted)

August 21, 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

☐ Alicia Henk

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

August 21, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Kansas, ss. County of Johnson

I, Alicia Henk, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Aug 21 2025

Date

Subscribed and Sworn to before me this 21 day of August 2025

Notary Public Signature

TRACEY BAILES
Notary Public, State of Kansas
My Appointment Expires
4-21-2029

(Seal)

First	Last	Job Assignment	Department
Adam	Allmon	362 - HR Director	362 - Human Resources
Christelle	Bielinis	363 - Director Information Technology	363 - Information Technology
Jon	Bunten	364 - Sr Counsel	364 - Legal
Kennette	Calhoun	166 - US Pharma QA Manager	166 - Quality Assurance
Sebastien	Deswarte	367 - CFO US	367 - Finance
Jennifer	Hake	220 - Director External Manufacturing North America	220 - Unapld Prod Cost/Campus Mgmt
Tammi	Hancock	381 - Regulatory Affairs Specialist	381 - Research Expenses Pharma
Alicia	Henk	381 - Director Pharmaceutical Pre-Approval Regulatory Affairs	381 - Research Expenses Pharma
Kathleen	Hernandez	381 - CMC Manager	381 - Research Expenses Pharma
Aaron	Kenkel	382 - QA Affiliate Quality Manager	382 - Pharmacovigilance
Dolina	Maharjan	260 - Manager Supply Chain	260 - Supply Chain
Jay	Pruett	368 - Chief Accounting Manager	368 - Accounting
Jean-Baptiste	Roubiere	371 - Director Purchasing	371 - Purchasing
Pam	Schneider	364 - Sr Paralegal	364 - Legal
Michael	Snyder	260 - Director Supply Chain Commercial	260 - Supply Chain
Tony	Strait	364 - Associate General Counsel	364 - Legal
Caitlin	Vogelsmeier	381 - Regulatory Affairs Specialist	381 - Research Expenses Pharma

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03684	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: K2M, Inc.

Physical Address: 600 Hope Parkway SE

City: Leesburg State: VA Zip: 20175

Mailing Address (if different from physical address): Same as physical.

City: State: Zip:

Telephone: 866-526-4171 Website:

Name of Designated Representative (DR): Megan Carnes

Licensing Company Email: megan.carnes@stryker.com DR Email: megan.carnes@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Surgical centers		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
See attached.	4/4/2023	AZ		Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
23-0627	Arizona State Board of Pharmacy

Reason/Charge
See attached.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
See attached.	See attached.

Name of Business/Industry/Entity
See attached.

Provide explanation below:

See attached.

Megan Carnes

Original Signature (electronic, copies or stamps not accepted)

March 14, 2025

Date

K2M, Inc. – Nevada Change of Ownership Application

Section 2: History of Company:

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?

Response: Yes, please see the attached consent agreement from the Arizona State Board of Pharmacy. While this is not related to the K2M, Inc. Leesburg, Virginia facility itself, it is Stryker-related discipline under previous ownership.

KRISTIN K. MAYES
Attorney General
Firm State Bar No. 14000

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
Assistant Attorney General
State Bar No. 020176
2005 N. Central Ave., SGD/LES
Phoenix, Arizona 85004-1592
Tel: (602) 542-7983
Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **STRYKER SUSTAINABILITY SOLUTIONS, INC. (Tempe)** **Applicant for Permit (M002150) as a Resident Virtual Manufacturer In the State of Arizona;** **STRYKER SUSTAINABILITY SOLUTIONS, INC. (Phoenix)** **Applicant for Permit (M002160) as a Resident Manufacturer In the State of Arizona;** **HOWMEDICA OSTEONICS, CORP. /STRYKER ORTHOPAEDICS (Tucson)** **Applicant for Permit (W003760) as a Resident Wholesaler In the State of Arizona;** **APPLICANTS**	Case No. 23-0627 **CONSENT AGREEMENT FOR ISSUANCE OF PERMITS AND ORDER FOR CIVIL PENALTY**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.* Stryker Sustainability Solutions ("Stryker Tempe" and "Stryker Phoenix") and Howmedica Osteonics Corp. ("Stryker Orthopaedics") collectively "Applicants", and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Applicant has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Applicant understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Applicant knowingly and voluntarily relinquishes all rights to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Applicant affirmatively agrees that this Consent Agreement shall be irrevocable. Applicant acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

4. Applicant understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Applicant understands this Consent Agreement deals with a Board Complaint involving allegations of unethical conduct against Applicant. The investigation into these allegations against Applicant shall be concluded upon the Board's execution of this Consent Agreement.

6. Applicant acknowledges and agrees that the acceptance of this Consent Agreement is solely to settle this Board matter and the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement and does not preclude the Board from instituting other proceedings as may be appropriate now or in the future.

7. Applicant understands that, except as provided in this Consent Agreement regarding the granting of permit applications and the resolution of unpermitted activity referenced in this Consent Agreement, this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

8. Furthermore, and notwithstanding any language in this Consent Agreement, this Consent Agreement does not preclude in any way any other state agency or officer or political subdivision of this state from instituting proceedings, investigating claims, or taking legal action as may be appropriate now or in the future relating to this matter other matters concerning Applicant, including violations of Arizona's Consumer Fraud Act. Applicant acknowledges that, other than with respect to the Board, this Consent Agreement makes no representations, implied or otherwise, about the views or intended actions of any other state agency or officer or political subdivision of the state relating to this matter or other matters concerning Applicant.

9. This Consent Agreement is effective only when signed by the Executive Director. If this Consent Agreement does not become effective it is withdrawn and shall

be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that if this case proceeds to hearing, Applicant shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. Applicant understands that any violation of this Consent Agreement constitutes unethical conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(16) and A.R.S. §32 – 1927.02(A) (1).

13. The parties understand and agree that Portable Document Format and facsimile copies of this Consent Agreement including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

14. Applicant agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY APPLICANT

Dated: 4/12/2024

On Behalf of
Stryker Sustainability Solutions, Inc.
and Howmedica Osteonics Corp.

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Stryker Sustainability Solutions, Inc. operated as a resident virtual manufacturer at two locations in the state of Arizona and Howmedica Osteonics Corp. operated as a wholesaler at one location in the state of Arizona. These three locations are not currently permitted in the state of Arizona.

3. During an inspection of a third Arizona-based Applicant location that held a permit but required a different type of permit, the Board identified potential unpermitted activity involving a different location and opened an investigation.

4. Applicant, through counsel, informed the Board that in fact, it was likely that several additional locations required permits. Applicant was already in the midst of a multi-year enterprise-wide project to rectify this oversight and voluntarily identified to the Board those locations within Arizona that Applicant believed required permitting.

5. In total, Applicant filed 28 permit applications with the Board and met with the Board on multiple occasions to discuss an efficient and orderly process to resolve all unpermitted activity at Applicant's locations that held or sought new permits.

6. Applicant acknowledges that it has manufactured and sold numerous devices from and into Arizona from unpermitted locations.

7. Applicant has 28 pending permit applications with the Board, which include administratively incomplete applications and applications that are substantively complete and ready for issuance. Three of these pending permit applications related to operations located within the State of Arizona.

CONCLUSIONS OF LAW

1. The Board asserts jurisdiction over the subject matter and over Applicant pursuant to A.R.S. § 32-1901 *et seq.*

2. The Board may deny a permit to an Applicant who has engaged in unethical conduct. A.R.S. § 32-1927.02(P).

3. The conduct and circumstances described above provide grounds for Board to impose discipline under A.R.S. §32-1927.03 which provides, that a person that resides in any other jurisdiction and that sells a prescription-only drug or device, within or into this state shall hold a valid board-issued permit and which allows the Board to impose a civil penalty for unpermitted activity.

ORDER

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT:

1. Stryker Sustainability Solutions, Inc. and Howmedica Osteonics Corp. shall jointly pay to the Board as a civil penalty the sum of Three Hundred Seventy-Five Thousand Dollars ($375,000/$125,000 per unpermitted location in this state). The civil penalty shall be paid in full to the Board within **Ninety (90) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. **IT IS FURTHER ORDERED, that the Board, through its Executive Director shall immediately grant and issue permits for all substantively complete applications and shall without delay, grant and issue permits for all applications that Applicant shall cause to be substantively completed or resubmitted to the Board in compliance with this Consent Agreement, subject to the following:**

   a. **The Board shall not grant any applications until such time Applicant pays the civil penalty as set forth above and any applicable permit fees.**

b. **The Board shall not grant any application until it has determined through its Executive Director, that the application is substantively complete and that the Applicant has met the minimum requirements for the permit.**

c. **The Board shall not consider any unpermitted activity at any location in deciding whether an application is administratively or substantively complete and shall not deny any application or pursue any other available remedy on the basis of unpermitted activity at any location before the effective date of this Consent Agreement.**

d. For each non-resident location, the Board shall issue a non-disciplinary advisory letter for unpermitted activity.

e. Upon Applicant's execution of and compliance with the terms in this consent agreement, including payment of the amount set forth in paragraph 1 above, all matters arising out of or made in connection with this consent agreement shall be fully resolved.

3. **By entering into the Consent Agreement, Applicant waives its right to appeal. In addition, the Board may seek further remedies as permitted by statute.**

4. With respect to the approximately twenty-five (25) various permit applications pending before the Board filed by or on behalf of Stryker Corporation or its subsidiaries, the parties acknowledge that the applications are in various stages of review by Board staff. Some applications are incomplete awaiting the receipt of additional information. Other applications were administratively closed because requested information was not timely received. Applicant has stated its intention to refile those applications and have all of its facilities come into compliance with Arizona law. **The parties agree that all applications that are otherwise complete and have met the**

requirements for licensure, shall be approved and the permits granted with Advisory Letters issued accordingly with each approved application.

5. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

DATED this 16th day of April, 2024.

ARIZONA STATE BOARD OF PHARMACY

By: Kam Gandhi
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FOREGOING FILED
this 16th day of April, 2024, with:

Arizona State Board of Pharmacy
1110 W. Washington St, Ste 260
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED BY
ELECTRONIC & REGULAR FIRST-CLASS MAIL
this 16th day of April, 2024, to:

Stryker Sustainability Solutions, Inc.
Attn: Marissa Richmond
4675 E. Cotton Center Blvd., Ste. 167
Phoenix, AZ 85040
marissa.richmond@stryker.com

Howmedica Osteonics Corp.
Attn: Cameron Caller
1023 Cherry Road
Memphis, TN 38117
cameron.caller@stryker.com

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Mark Boesen
Michael Raine
Boesen & Snow Law
8501 E. Princess Dr., Ste. 220
Scottsdale, AZ 85255
MBoesen@BSLawUSA.com
MRaine@BSLawUSA.com

COPY OF THE FOREGOING E-MAILED
this 16th day of April, 2024 to:

Jeanne Galvin Seth T. Hargraves
Assistant Attorneys General
2005 N, Central Ave, SGD/LES
Phoenix, Arizona 85004-1592
Attorney for the State
LicensingEnforcement@azag.gov

JM Harrell

Doc #11915034

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Michigan

Parent Company (if any): _____

Corporation Name: Stryker Corporation

Mailing Address: 1741 Stryker Way

City: Portage State: MI Zip: 49002

Telephone: _____ Email: _____

Contact Person Name: Austin Ke

Date of SEC Registration: 1979 | SEC Registration Number: 001-13149 | Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): VB Spine LLC

Corporation/Organization Name: K2M, iNC

Mailing Address: 600 Hope Parkway SE

City: Leeburg State: VA Zip: 20175

Telephone: (212) 583-9700 Email: jchan@vbllc.com

Contact Person Name: Marc Viscogliosi

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

K2M, Inc.

Facility Name

Megan Carnes

Print Name of Authorized Person Submitting Application

Megan Carnes

Original signature of Authorized Person (copies or stamps not accepted)

March 14, 2025

Date

Board Use Only	Date Received: 3/19/25	Amount: $1000 CC

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
K2M, INC.
600 Hope Pkwy SE
Leesburg, VA 20175
Registration Number: 3004774118
FEI Number*: 3008599177
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
STRYKER CORP.[6]
1901 Romence Pkwy
Portage, MI US 49002
Owner/Operator Number: 1811755[7]

Official Correspondent:
Oonagh Lahiff
2 Pearl Ct
Allendale, NJ 07401
Phone: 001-201-8243302

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperator
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Page Last Updated: 10/21/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1811755&OwnerOperator

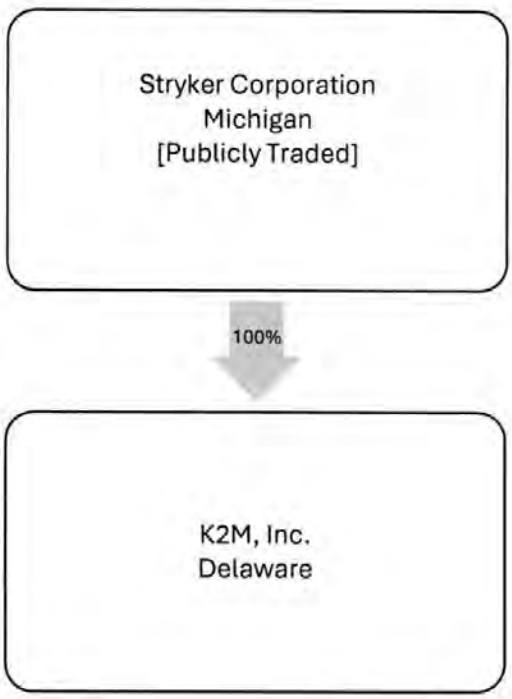
K2M, Inc.

Officer List effective April 1, 2025

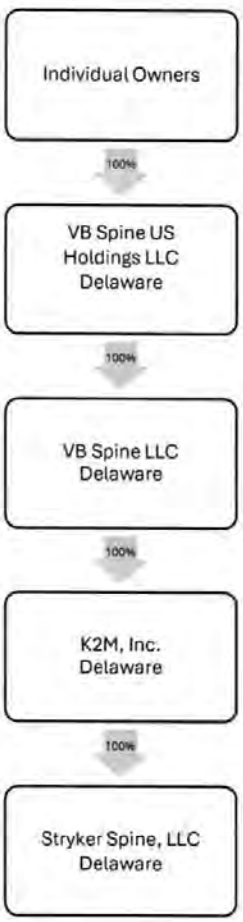
Name	Title
Marc Richard Viscogliosi	co-Chief Executive Officer
John Joseph Viscogliosi	co-Chief Executive Officer
Anthony Gaetano Viscogliosi	co-Chief Executive Officer
Joseph Chan	Secretary

Organizational Chart – K2M, Inc.

Pre-Organizational Chart



Post-Organizational Chart



Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "K2M, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF FORMATION, FILED THE TWENTY-EIGHTH DAY OF JANUARY, A.D. 2004, AT 3:41 O`CLOCK P.M.

RESTATED CERTIFICATE, CHANGING ITS NAME FROM "K2 MEDICAL, LLC" TO "K2M, LLC", FILED THE FIRST DAY OF DECEMBER, A.D. 2004, AT 3:26 O`CLOCK P.M.

CERTIFICATE OF CONVERSION, CHANGING ITS NAME FROM "K2M, LLC" TO "K2M, INC.", FILED THE FIFTEENTH DAY OF JUNE, A.D. 2006, AT 6:27 O`CLOCK P.M.

CERTIFICATE OF INCORPORATION, FILED THE FIFTEENTH DAY OF JUNE, A.D. 2006, AT 6:27 O`CLOCK P.M.

RESTATED CERTIFICATE, FILED THE TWENTY-SEVENTH DAY OF MARCH, A.D. 2008, AT 12:29 O`CLOCK P.M.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3757904 8310

SR# 20254808878

Authentication: 205555813

Date: 12-09-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to certify:

Entity Name: STRYKER CORPORATION
Entity ID#: 800151233
Entity Type: Domestic Profit Corporation
Initial Filing Date: 02/20/1946
Delayed Effective Date:
Formation Jurisdiction: Michigan
Act Formed Under: 327-1931 Michigan General Corporation Act

That the above referenced entity was validly incorporated and said corporation is validly in existence under the laws of this state.

This certificate is issued in conformity with the Act it is formed under, to attest to the fact that the company is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, on October 13, 2025.

Linda Clegg

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

Certificate Number: 30877
Verify this certificate at: www.michigan.gov/corpverifycertificate

Virginia Department of Health Professions License Lookup

Current as of 05/19/2025 10:15

License Information

License Number	0216000200
Occupation	Warehouser
Name	K2M, Inc.
Address	Megan Carnes 600 Hope Parkway SE Leesburg, VA 20175
Initial License Date	05/12/2023
Expire Date	02/28/2026
License Status	Current Active
Additional Public Information*	No

Back to License Lookup Result

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

** "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.*

Back to License Lookup

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
04/01/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Fabricant & Fabricant Inc. 1251 Old Northern Boulevard P.O. Box 9004 Roslyn NY 11576	CONTACT NAME: Meenakshi Luthra PHONE (A/C, No, Ext): (516) 621-9000 FAX (A/C, No): (516) 621-0092 E-MAIL ADDRESS: meenakshil@fabricantinsurance.com
INSURED VB Spine LLC 505 Park Avenue 14th Floor New York NY 10022	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Hartford Fire Ins. Co. — 19682 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** Master '25-'26 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [X] CLAIMS-MADE [ ] OCCUR DEDUCTIBLE: $250,000 RETRO DATE: 04/01/2025 GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER			12UGABP7GZ5-037	04/01/2025	04/01/2026	EACH OCCURRENCE	$ 20,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
							GENERAL AGGREGATE	$
							PRODUCTS - COMP/OP AGG	$ 20,000,000
								$
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					[ ] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

K2M, Inc. and its affiliated companies are wholly owned by VB Spine and named under the referenced policy effective 4/1/25.

The policy referenced above covers actual or alleged product defects arising out of VB Spine's negligence in design, manufacturing, or handling products distributed by authorized sales representatives.
Limits are in US Dollars.
Subject to the provisions of the policy, Emergo Europe B.V., as an agent for K2M, Inc. is included as an Additional Insured under the referenced policy to the extent required by the European Authorized Representative Agreement between the parties.

CERTIFICATE HOLDER

Emergo Europe B.V.
Westervoortsedijk 60
Arnhem GE 6827 NLD

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 12BSBJI8887

Application/License No. WH03684

K2M, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 600 Hope Parkway SE, Leesburg, VA 20175 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 8888 East Raintree Drive, Scottsdale, AZ 85260 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

12B9BJI8887

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 2025.

APPLICANT/PRINCIPAL

K2M, Inc.

Authorized Representative

Joseph Chan

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Robert Fabricant, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Timothy W. Ormsby

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
cell: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: FOUNDATION RISK PARTNERS CORP
Agency Code: 12-122310

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Robert Fabricant

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 12BSBJI8887
Naming K2M, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of April 21, 2025.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG K2M, Inc. MDEG License # (if applicable) WH03684

Physical Address 600 Hope Parkway SE

City Leesburg State VA Zip 20175

Mailing Address (if different from physical address) Same as physical.

City _____ State _____ Zip _____

Telephone 866-526-4171 Website _____

Licensing Company Email megan.carnes@stryker.com

Section 2: Personal Information

First Megan Middle _____ Last Carnes

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☐ F ☐ X

Mailing Address 600 Hope Parkway SE

City Leesburg State VA Zip 20175

Telephone 866-526-4171 Email megan.carnes@stryker.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Virginia		2006-2008	
Address	**City**	**State**	**Zip**
PO Box 4000203	Charlottesville	VA	22904
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Loudoun County High School		1999-2004	
Address	**City**	**State**	**Zip**
415 Dry Mill Road, SW	Leesburg	VA	20175
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/24 - 8/15	[redacted]	Leesburg	VA	[redacted]
7/15 - 8/09	[redacted]	Leesburg	VA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
K2M, Inc.			May 2008 - Present	
Business Address		**City**	**State**	**Zip**
600 Hope Parkway SE		Leesburg	VA	20175
Phone	**Title**		**Number of Employed Hours**	
866-526-4171	Manager-Quality Assurance		+6000 hours	
Description of Duties				
See attached.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Megan Carnes, **certify that as the MDEG Administrator for**

K2M, Inc.,

that I (initial that you have read and meet the following requirements):

1. MEC Have a high school diploma or its equivalent;
2. MEC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MEC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MEC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Megan Carnes
Print Name (First, Last)

Megan Carnes
Original Signature (electronic, copies or stamps not accepted)

March 14, 2025
Date

Board Use Only	Date Received:

MEGAN CARNES [redacted]

EDUCATION

University of Maryland Smith School of Business, College Park, MD 2012
Masters of Business Administration

University of Virginia School of Engineering, Charlottesville, VA 2008
Bachelors of Science: Mechanical Engineering, Minors: Aerospace & Biomedical Engineering

WORK EXPERIENCE

Manager, Quality Assurance, *Stryker, Leesburg, VA* May 2021 – Present

- Lead a high performing team of full time Quality Engineers, Manufacturing Engineers, Engineering/Calibration Technicians and supporting contractors, with 16 reports and foster a culture of excellence and continuous improvement.
- Ensured Key Performance Indicators (KPIs) are achieved and surpassed year over year, focusing on Non-Conformances (NC)/Corrective and Preventive Actions (CAPA), Defects per Million (DPM), Escapes, Product Mix, and Use As Is (UAIs), demonstrating a commitment to quality and efficiency.
- Driven significant quality enhancements that resulted in 63% Escape Reduction in three years as a result of 133 CAPAs Implemented and 400 NCs Executed for internal and external issues.
- Supplier Certification of 1,500 high volume SKUs has led to $240,000 in annual variable head count cost savings.
- Achieved a remarkable 79% reduction in Defects per Million (DPM) from 2018 to 2023 (from 14,802 to 3,125), highlighting a strong focus on quality improvement and defect reduction.
- 12,000 active SKUs are manufactured by Leesburg, with 86% of all product Supplier Certified or with a Streamlined Inspection Plan, allowing for increased product throughput while maintaining the highest quality by making informed decisions based on historical data.
- Manage Supplier Initiated Change Request process that requires knowledge of manufacturing processes, pFMEA, IQ/OQ/PQ, FAI, MSAs, Capability Studies to execute Production Part Approval Process documentation
- Supported the remediation of supplier documentation and inspection plans in response to the European Union Medical Device Regulation (EU MDR), Brexit, and changes in Notified Bodies, ensuring compliance and continuous market access.
- Supported supplier compliance to ISO 19227 for implant manufacturing cleaning, enhancing product safety and quality
- Demonstrated exceptional communication and presentation skills, effectively influencing change among both technical and non-technical stakeholders.
- Excel in a high-urgency environment, leveraging strong analytical and problem-solving skills to manage multiple complex tasks simultaneously with high efficiency.
- Increased Quality Gallup Q12 Engagement scores by 25% in two years.
- Served as the Stryker Women's Network ERG East Region Lead for 2024-2025, overseeing four sites, and as the Spine Lead in 2021-2022, demonstrating leadership in diversity and inclusion initiatives.

Associate Manager, Quality Assurance, *Stryker, Leesburg, VA* February 2019 – May 2021

- Directed a team of eight engineers/technicians overseeing an ISO 13485 and 21 CFR 820 compliant GQO Quality Assurance program for the Leesburg, VA and Allendale, NJ Site.
- Integrated Stryker and K2M Quality Management Systems, including developing processes and procedures for supplier controls, NC/CAPA, validation, inspection and calibration.
- Managed an ASL with over 300 suppliers and supplier processes/products for implants, instruments and biologics.
- Managed Material Review Board that receives on average 2,000 Quarantine Tickets/year.
- Directed the Supplier Initiated Change Request process, ensuring timely and appropriate actions are taken to resolve issues with minimal business impact, thereby maintaining continuous supply chain efficiency.
- Achieved a 98% reduction in UAIs through strategic internal process improvements, ensuring comprehensive communication with suppliers and prompt resolution of issues, significantly enhancing operational efficiency.
- Created and implemented a Quality engagement program that includes a monthly Most Valuable Person (MVP) program with peer-to-peer nominations, fostering a culture of recognition and engagement among the quality team.
- Served as the Spine Events Lead for Stryker Women's Network ERG during 2019-2020.

Supplier Quality Manager, *K2M Inc., Leesburg, VA* August 2018 - February 2019

- Managed a team of three engineers/technicians responsible for leading the K2M Leesburg Supplier Quality program and executing associated systems, processes, programs/initiatives, practices, and metrics for ensuring and improving overall Supplier Quality performance for over 50 Contract Manufacturers and OEMs.

- Fostered effective collaboration between supply chain management, quality control, engineering, R&D, and regulatory departments to set and enforce supplier quality and performance guidelines.
- Spearheaded the supplier audit program, facilitating thorough investigations, reporting on corrective actions (including SCARS and CAPA's) and ensuring timely responses from suppliers.
- Developed risk-based programs and procedures focused on supplier transfers, qualifications, and performance enhancements to increase supplier productivity and efficiency.
- Played a pivotal role in the supplier selection process, evaluating potential partners, and managing the supplier qualification process to ensure high standards of quality and reliability.
- Managed the Supplier Process Review (SPR) process, supervising the validations and qualifications of supplier manufacturing processes to guarantee superior quality in part/component manufacturing.

Senior Project Engineer, *K2M Inc., Leesburg, VA* March 2016 - August 2018

- Manage a team of four full time engineers who develop and maintain over 20 product lines including Interbodies, Corpectomy Cages, Cervical and Lumbar Plates Systems producing over $37 million in 2017 revenue.
- Develop complex implant systems with additively and traditionally manufactured components.
- Coordinate cross functional projects with marketing, quality, regulatory and supply teams to gain 510(k) clearances and CE Markings.
- Review and approve design controls, including drawings, risk management documents per ISO 14971, DHF's, DMR's, traceability matrixes and test reports.
- Developed mentorship program in 2017 for engineers to support co-ops during rotations. Outstanding reviews of the program lead to companywide implementation in 2018.
- Lead monthly trainings with 20+ employees to review legacy systems and share lessons learned.
- Interact and engage with suppliers to improve component assembly processes and implant design.
- Write clinical evaluation reports to support device equivalence and help maintain technical files and essential requirements.
- Interface with surgeons to discuss new product development and feedback from clinical use.
- Five patents issued, four patents pending.

Project Engineer, *K2M Inc., Leesburg, VA* March 2014 - March 2016

- Lead engineer on Interbody, Plates and Standalone Interbodies.
- Assist in writing 510(k)'s for FDA regulatory clearances.
- Manage multiple product lines while simultaneously supporting legacy products.
- Lead and coordinate new product development with marketing and engineer teams.
- Conduct team meetings with K2M Senior Executives and project teams according to ISO and FDA requirements.
- Create and maintain risk management documentation for individual product lines.

Senior Development Engineer, *K2M Inc., Leesburg, VA* May 2011 – March 2014

- Engineer on Interbody, Plates and Standalone Interbodies
- Manage multiple product lines while simultaneously supporting legacy products.
- Work with international teams to develop specific implants and instrumentation for Australia and UK surgeons.
- Test implants to ASTM standards and submit 510(k)'s to the FDA for regulatory clearance.
- Design and perform verification and validation testing on implants/instruments.
- International and Domestic travel to evaluate new implants/instrumentation in surgery and cadavers.
- Communicate and troubleshoot potential challenges with vendors during product manufacturing.
- Coordinated the evaluation launch of the Blue Ridge Hybrid Plate in less than 90 days.
- Support five major product lines that produced over $25 million in revenue.

Development Engineer, *K2M Inc., Leesburg, VA* May 2008 – May 2011

- Support engineer for product lines focusing on plates and interbodies for spine surgery.
- Create complex models and drawings for implants/instruments with SolidWorks utilizing GD&T.
- Updated aging product lines and made rolling changes to adapt to the needs of customers.
- Route drawings for approval in MasterControl, document control software.

Engineering Intern, *K2M Inc., Leesburg, VA* Summers 2005 - 2007

- Assisted Engineers with SolidWorks models and drawings.
- Inspected instruments and implants for quality control.

COMPUTER SKILLS

JDE, SolidWorks, MasterControl, Microsoft Office Suite

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler K2M, Inc.

Pharmacy/Wholesaler License # (if applicable) WH03684

Physical Address 600 Hope Parkway SE

City Leesburg State VA Zip 20175

Mailing Address (if different from physical address) Same as physical.

City _____ State _____ Zip _____

Telephone 866-526-4171 Website _____

Licensing Company Email megan.carnes@stryker.com

Section 2: Personal Information

First Megan Middle _____ Last Carnes

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 600 Hope Parkway SE

City Leesburg State VA Zip 20175

Telephone 866-526-4171 Email megan.carnes@stryker.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Virginia		2006-2008	
Address	**City**	**State**	**Zip**
PO Box 4000203	Charlottesville	VA	22904
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Loudoun County High School		1999-2004	
Address	**City**	**State**	**Zip**
415 Dry Mill Road, SW	Leesburg	VA	20175
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
4/24 - 8/15	[redacted]	Leesburg	VA	[redacted]
7/15 - 8/09	[redacted]	Leesburg	VA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
K2M, Inc.			May 2008 - Present	
Business Address		**City**	**State**	**Zip**
600 Hope Parkway SE		Leesburg	VA	20175
Phone	**Title**		**Number of Employed Hours**	
866-526-4171	Manager-Quality Assurance		+6000 hours	
Description of Duties				
See attached.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Megan Carnes, **certify that as the designated representative for**

K2M, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MEC I am at least 21 years of age;
3. MEC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MEC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MEC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MEC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MEC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Megan Carnes
Print Name (First, Last)

Megan Carnes
Original Signature (electronic, copies or stamps not accepted)

March 14, 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Megan Carnes

Print Name (First, Last)

Megan Carnes — March 14, 2025

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Virginia, ss. County of Loudoun

I, Megan Carnes, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Megan Carnes — March 14, 2025

Original Signature — **Date**

Subscribed and Sworn to before me this 14th day of March 2025

Diana Lee Stonehouse

Notary Public Signature

Diana Lee Stonehouse
NOTARY PUBLIC
Commonwealth of Virginia
Reg. # 7352194
My Comm. Expires June 30, 2026

(Seal)

First Name	Last Name	Business Title	Employee Status Descr Long
Mohamed	Abadrabo	Inventory Control Technician I	Active
Omid	Abbarin	Senior Manager, IT BP	Active
Hakam	Abu Dawwas	Driver	Active
Mohaned	Abujennah	Staff NPI Quality Engineer	Active
Rachel	Achurra	AM, Commercial Ops	Active
Alyssa	Ader	Quality Engineer	Active
Hena	Afshari	Commercial Ops Specialist	Active
Max	Agbayani	Quality Control Inspect. Tech	Active
Katelynne	Agnetti	Medical Education Lead	Active
Bryan	Ahrens	Sr. Sales Representative	Active
Christian	Akers	Sales Representative	Active
Briggs	Akin	Sales Associate	Active
Racquel	Aking	AM, Post Market Surveillance	Active
Mohamed	Alaas	Lead Tech., Engineering RL	Active
Laura	Alders	Inventory Control Tech. III	Active
Sam	ALFIERI	Sales Representative	Active
Teri	Allard	Finance Associate, Invoicing	Active
Richard	Allen	Lead Driver	Active
Shane	Allen	Sales Representative	Active
Morgan	Allin	Supervisor, Quality Control	Active
Matt	Allison	Area Sales Director	Active
Ashley	Almodovar	Technician Loaner I	Active
Tetiana	Alonso	Field Operations Team Leader	Active
Marc	Alperen	Sales Associate	Active
Tony	Alvarenga	Manager; Operations	Active
Patricia	Alvarenga	Finance Specialist, Invoicing	Active
Victor	Alvarenga	Lead, IT Solution Support	Active
Alicia	Ameur	Finance Specialist, Invoicing	Active
Darren	Anders	Sales Associate	Active
Aaron	Anderson	Commercial Ops Associate	Active
Emily	Anderson	Portfolio Associate	Active
Matthew	Angelone	Sales Representative	Active
Brian	Aparo	Regional Sales Manager	Active
Pauline	Apisitpaisarn	Inventory Control Tech. II	Active
Alena	Aranda	Senior Lead, IT Business An.	Active
Eric	Armbruster	Sr. Sales Representative	Active
Craig	Armstrong	SM, Customer Experience	Active
Katie	Armstrong	SM, Education Associate	Active
Rida	Arshad	Senior Advanced Qual. Engineer	Active
Matt	Ashman	AM, Master Data Governance	Active
Martin	Ayers	Associate Manager, R&D	Active
Kole	Ayi	Sr. Sales Representative	Active
Jimmy	Bacon	Regional Sales Manager	Active
Keith	Baker	Sr. Sales Representative	Active
Jerry	Bardol	Sales Associate	Active
Olivia	Bark	Development Engineer	Active
Nicholas	Barka	Sr. Sales Representative	Active
Skip	Barkley	Sr. Spine Specialist	Active
Callen	Barlik	Product Manager	Active
Paget	Barlow	Sales Associate	Active
Liam	Barnes	Staff Engineer	Active
Matthew	Bartlow	Sr. Sales Representative	Active
Mishu	Barua	Project Engineer	Active
Jack	Bates	Spine Specialist	Active
Samay	Bayat	Quality Control Technician I	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Anastasia	Bazil	Manager, Sales Operations	Active
Jeremy	Beavin	Supply Planner	Active
Joel	Beavin	Senior Field Count Associate	Active
Emmet	Bell	Sales Representative	Active
Tondrae	Bell SR	Driver	Active
Damon	Belloni	Principal Quality Systems Sp.	Active
Caity	Benham	Contract Activation Analyst	Active
Sara	Benner	Inventory Control Technician I	Active
Ashley	Bergen-Stewart	Lead Analyst, Data Analytics	Active
Michael	Berlin	Sr. Sales Representative	Active
Obrien	Berry	Sr. Sales Representative	Active
Nick	Betts	Field Operations Team Leader	Active
John	Bewley	CNC Programmer/Machinist	Active
Aparna	Bharath Kumar	Senior Staff Data Analyst	Active
Brian	Bickell	Regional Sales Manager	Active
Jacob	Birkholz	Staff Quality Data Engineer	Active
Pragya	Bista	SM, Regulatory Affairs	Active
Rakshya	Bista	Program Manager, CQR	Active
Petra	Blake	Commercial Ops Associate	Active
Madison	Boman	Lead Analyst, Sales Operations	Active
Alyse	Borelli	Manager, Clinical Affairs	Active
Natalie	Bost	Finance Specialist, Invoicing	Active
Thomas	Bowe	Spine Specialist	Active
Zach	Bowen	Sr. Sales Representative	Active
Clint	Boyd JR	SM, Product Engineering	Active
Pamela	Brenes	Quality Systems Specialist	Active
Mario	Brito	Loaner Technician II	Active
Rebecca	Brooks	Director, Downstream Marketing	Active
George	Brooks JR	Regional Sales Manager	Active
Morgan	Brophy	Sr. Staff R&A Sp.	Active
Gregory	Brown	Sr. Program Mgr., PMO & Strat.	Active
Shelly	Brown	Sr. Spine Specialist	Active
Molly	Brown	Clinical Program Manager	Active
Tim	Brown	Sales Associate	Active
Jenny	Brusehaber	Commercial Ops Team Lead	Active
Blake	Buchanan	Lead Analyst, Finance	Active
Peter	Budway	CNC Programmer/Machinist II	Active
Nick	Buras	Commercial Ops Specialist	Active
Katie	Burch	Commercial Ops Specialist	Active
Meghan	Burns	Portfolio Manager	Active
Kurt	Busscher	Sr. Sales Representative	Active
Erin	Butler	Senior Marketing Associate	Active
Mason	Butler	Team Member, Driver	Active
Kevin	Cabatu	Field Operations Technician II	Active
Andrew	Calcaterra JR	Sr. Advanced Quality Engineer	Active
Lauren	Caldwell	AM, Field Ops	Active
Eric	Campbell	Sr. Sales Representative	Active
Michael	Campbell	Senior Manager, Sourcing	Active
John	Campe	Product Packager I	Active
Neil	Campe	Inventory Control Specialist	Active
Thomas	Canale	Area Vice President	Active
Jose	Canchola	Sr. Spine Specialist	Active
Christina	Cannon	Spine Experience Program Mgr.	Active
Derek	CAPPS	Sr. Sales Representative	Active
Brenna	Carbone	Quality Engineer, Post Market	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Megan	Carnes	SM, Quality Assurance	Active
Callie	Carpenter	Staff Engineer	Active
Scott	Carpenter	Loaner Specialist	Active
Raven	Carter	Senior Clinical Data Sp.	Active
Justin	Casey	Spine Specialist	Active
Cathy	Castle	Finance Associate, Invoicing	Active
Ashlynn	Catalan	Senior Analyst, Data Analytics	Active
Eric	Cecco	Staff Engineer	Active
Jasmine	Cerpas	Lead HR Representative	Active
Sam	Chaar	Sr. Staff Eng., Advanced Ops	Active
Jchan@Vbllc	Chan	SVP, General Counsel	Active
Sathya	CHANDRN	Senior Quality Systems Sp.	Active
Katelyn	Chase	Director, Sales Operations	Active
Jeffrey	Chavez	Driver	Active
Lisa	Chen	Spine Specialist	Active
Danilo	Ching	Loaner Technician III	Active
Theo	Choi	Senior Staff Engineer	Active
Nuzhat	Chowdhury	Senior Microbiologist	Active
Bryan	Clancy	Sr. Sales Representative	Active
Alessandra	Clark	Sr. Clinical Contract Assoc.	Active
Tyler	Clarkson	Project Manager, Advanced Ops	Active
Izzy	Clavenna	Sales Associate	Active
Andrew	Clavio	Inventory Control Tech. II	Active
Zachary	Clifford	Sales Representative	Active
Chelsea	Coburn	Regional Sales Manager	Active
Karen	Colletti	Finance Specialist, Invoicing	Active
Colton	Collins	Sales Associate	Active
Matt	Collins	Regional Sales Manager	Active
Sawyer	Collins	Production Team Leader	Active
Terry	Connor	Senior Supervisor, Production	Active
Lorie	Continelli	Sr. Director, R&D	Active
Scott	Converse	Sr. Sales Representative	Active
Angie	Cooke	Senior Coordinator	Active
Shannon	Cool	Fulfillment Technician II	Active
Brooks	Cooper	Loaner Technician I	Active
Reese	Cooper	Staff Quality Engineer	Active
Elisha	Corbin	Field Operations Technician II	Active
Ryan	Corley	C&E Lead - Bioskills Lab	Active
Bill	Corpas	Sales Representative	Active
Daryl	Creamer JR	Product Packaging Specialist	Active
Dylan	Creasey	Spine Specialist	Active
David	Cremin	Sales Representative	Active
Chad	Croteau	Spine Specialist	Active
Cesar	Cubillos	Data Engineer	Active
Brian	Curry	Associate Manager, Sourcing	Active
Brittney	D'Aloia	Sr. Supervisor, Commercial Ops	Active
Jackson	Dana	Inventory Control Technician I	Active
Sharon	Dana	Finance Specialist, Invoicing	Active
Sevack	Danadian	Senior Quality Systems Sp.	Active
Kristina	Daoud	Senior Regulatory Affairs Sp.	Active
Sarah	Darnell	Senior PMS Analyst	Active
Emily	DAVIDSON	Senior Portfolio Associate	Active
Jeremy	Davis	Sr. Sales Representative	Active
Petra	DAVIS	Sales Representative	Active
Angie	Dawson	Senior EHS Technician	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Jason	Dawson	Prod. Pckg. II, Pckg.- Skilled	Active
Ryan	Dawson	Quality Control Inspector II	Active
Greg	Day	Assoc. Supervisor, Production	Active
Caity	De Angelus	Project Manager, Advanced Ops	Active
Kaylah	De Gree	AM, Downstream Marketing	Active
Pat	DeLong	Area Vice President	Active
Trinity	Denholm	Sales Representative	Active
Larry	Dennis	AM, Product Engineering	Active
Luis	Depina	Field Operations Technician II	Active
Marco	Di Rocco	Field Operations Technician II	Active
Tanc	DICKENS	Sr. Sales Representative	Active
Derek	Diehl	Spine Specialist	Active
Michael	Dill	Senior Staff NC/CAPA Sp.	Active
Caleb	DIPRETE	Sr. Process Dev. Engineer	Active
Brent	Dlugach	Director, Strategic Sales	Active
Jeff	Dobies JR	Production Team Lead	Active
Mike	Doerr	Regional Sales Manager	Active
Michael	Dolegiewitz	Staff Engineer, Engineering	Active
Lori	Dombrowski	Senior Staff Designer	Active
Conor	Donohue	Sr. Sales Representative	Active
Andy	Dorich	Spine Specialist	Active
Teresa	Driscoll	Sales Coordinator	Active
Kelly	Dye	Finance Associate, Invoicing	Active
Miguel	Echarte	Area Sales Director	Active
Sean	Edson	Sales Representative	Active
Carl	Edwards	Reverse Technician I	Active
Onika	Edwards	Inventory Control Tech. II	Active
Drew	Eibner	Sr. Sales Representative	Active
Allison	Elkins	Inventory Control Tech. II	Active
Riley	Elkins	Inventory Control Technician	Active
Sydnee	Elkins	Loaner Technician II	Active
Patrick	Ennis	Regional Sales Manager	Active
Matt	Estrada	Production Team Lead	Active
Latonya	Evans	Quality Systems Specialist	Active
Sedale	Evans	Director, Manufacturing	Active
Samantha	Fatkin	Sales Associate	Active
Esther	Fatokun	Contract Perform. Mngt. Anlst.	Active
Keith	Fava	Director, PMO	Active
Taylor	Fawcett	Sales Associate	Active
Alexander	Feliu	Inventory Control Technician I	Active
Shianna	Fenner	Comm. Ops Team Lead, Global	Active
Adriana	Feraco	Product Packager II	Active
Hope	Ferdinando	Staff Advanced Quality Eng.	Active
Mferguson@Vbllc	Ferguson	Executive Assistant	Active
Jessica	Ferrell	Finance Associate, Invoicing	Active
Hannah	Floyd	Commercial Ops Associate	Active
Cynthia	Forgione	Finance Specialist, Invoicing	Active
Nicole	Foti	AM, Meeting Planning and Even.	Active
Walter	Fraidenburg	Sr. Sales Representative	Active
John	Frank	Sr. Sales Representative	Active
Amy	Frankenberger	Senior Manager, Finance	Active
Catherine	Franzen	Sales Coordinator	Active
Brian	Frazier	Spine Specialist	Active
Joseph	Fredericks	Staff Engineer	Active
David	Freeland	Inventory Control Technician	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Danny	Friedman	Field Scheduler	Active
Cristian	Fuentes	Driver	Active
Alex	Funck	CNC Programmer/Machinist	Active
Shelly	Furman	Finance Specialist, Invoicing	Active
Brittany	Gadigian	Senior Staff Advanced QE	Active
Michael	Gaintner	Senior Director, PMO	Active
Michaela	Galati	Data Analyst	Active
Aaron	Galvan	Field Operations Technician II	Active
Marco	Galvez	Field Operations Technician I	Active
Tennie	Gandara	Marketing Communications Lead	Active
Cori	Garcia	Portfolio Manager	Active
Craig	Garcia	Sr. Spine Specialist	Active
Nicholas	Gardner	Spine Specialist	Active
Graham	Garlasco	Sales Representative	Active
Isabel	GARZA	Staff Regulatory Affairs Sp.	Active
Jessie	Garza	Sr. Sales Representative	Active
Jalen	Gaudet	Delivery Driver	Active
Jack	Gaylord	Sales Associate	Active
Daniel	Genovese	Senior Staff Engineer	Active
Zachary	George	Spine Specialist	Active
Tashan	GILLIAN	Sr. Field Inv. Coordinator	Active
Brian	Gillis	Senior Field Count Associate	Active
Scott	Gilson	Sales Associate	Active
Cgioffre@Vbllc	Gioffre	Director BD & Transformation	Active
Joseph	Giordano JR	Senior Staff Engineer	Active
Lauren	Gittelman	Project Manager, Planning	Active
Andrew	Gladden	Strategic Sales Manager	Active
Jason	Glynn	Regional Sales Manager	Active
Daniel	Godsil	Sales Representative	Active
Satchel	Gomez Driscoll	Sales Representative	Active
Jesus	Gongora Rocha	Inventory Control Tech. II	Active
Torre	Goodman	Trusted Advisor	Active
Sgormick@Spinebiopharma	Gormick	Executive/Personal Assistant	Active
Christal	Gotimer	Staff Engineer, Advanced Ops	Active
Tiya	Grabowski	Fin. Representative, Invoicing	Active
Shawn	Graham	Manager, Upstream Marketing	Active
Beau	Gray	Sr. Sales Representative	Active
Michael	Greco	Staff Qual. Eng., Post Market	Active
Adrielle	Green	Associate Manager, Finance	Active
Natreal	Green	Field Operations Technician I	Active
Steven	Greendyk	Senior Staff Engineer	Active
Jeffrey	Greengrass	Sr. Sales Representative	Active
Kristin	Greenquist	Sales Representative	Active
Megan	Griffin	Senior Staff Medical Writer	Active
Jamie	Griffith	Assoc. Project Mgr. Prod. Eng.	Active
Michael	Grutkowski	AM, Commercial Ops	Active
Hannah	Gurnavage	Staff Quality Systems Sp.	Active
Christopher	GUTMAN	Sr. Sales Representative	Active
William	Guzman	Machinist II	Active
Quera	Gwaltney	Regulatory Affairs Analyst	Active
Effa	Gyamfi	Clinical Quality Associate	Active
Kelly	Haddox	Lead TA Business Partner	Active
Ailon	Haileyesus	Staff Engineer	Active
Luke	Hains	Spine Specialist	Active
Joseph	Hall	Strategic Sales Manager	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Jim	Ham	Director, Product Engineering	Active
Wael	Hamade	Sr. Sales Representative	Active
Greg	Hand	Field Operations Team Leader	Active
Jim	Harding SR	Sr. Sales Representative	Active
Benjamin	HARPER	Set Assembly Technician II	Active
Allison	Harris	Staff Engineer	Active
Cheston	Harris	Sr. Sales Representative	Active
Austin	Harrison	Commercial Ops Specialist	Active
Darryl	Harrison	Field Operations Technician I	Active
Aaron	Hartlove	Inventory Control Tech. III	Active
Todd	Harvey	Commercial Ops Associate	Active
Basma	Hassan	Quality Engineer	Active
Derek	Hasselhoff	Sr. Sales Representative	Active
Brett	Hawken	Sr. Sales Representative	Active
Hannah	Heberle-Rose	Project Manager, PMO	Active
Corey	Heinz	Sr. Sales Representative	Active
Jacob	Heinz	Sr. Sales Representative	Active
Darlene	Hess	Receiving Technician I	Active
Jack	Higgins	Sales Associate	Active
Jason	Hill	Commercial Ops Associate	Active
Katie	Hill	Sales Associate	Active
Jared	Hocker	Sales Associate	Active
Nicole	Hodgson	Finance Lead, Invoicing	Active
Bill	Holbrook	Sr. Sales Representative	Active
Jordan	Holder	Senior Staff Engineer	Active
Chloe	Holland	Spine Specialist	Active
Katherine	Hollar	Senior Development Engineer	Active
Tim	Holtz	Director, Sourcing	Active
Maegan	Hosner	Commercial Ops Associate	Active
Drew	Howard	Regional Sales Manager	Active
Taylor	Hubert	Commercial Ops Specialist	Active
Donald	Huckaba	Sr. Director, Commercial Ops	Active
Bryan	HUFFAKER	Sales Representative	Active
Guy	Hughes	Senior Director, IT BP, Spine	Active
Niki	Infantino	Manager, HRBP	Active
David	Irwin	Director, IT Business Partner	Active
Landon	Irwin	Inventory Control Technician I	Active
Jessica	Iwinski	Sr. Sales Representative	Active
Eva	James	Senior Regulatory Affairs Sp.	Active
June	Jeffers	Marketing Coordinator Lead	Active
Evan	Jenkins	Supervisor, Production	Active
Dane	Johannessen	Senior Staff Engineer	Active
Curley	Johnson	Sr. Sales Representative	Active
Darren	Johnson	Sales Associate	Active
Ethan	Johnson	Sr. Sales Representative	Active
Jim	Johnson	Sr. Sales Representative	Active
Joshua	Johnson	VP, General Mgr., Core Spine	Active
Connor	Jones	Sr. Engineer, Manufacturing	Active
Diana	Joseph	Product Manager	Active
Daniel	Journey	Sales Associate	Active
Sachie	Kakehi	Staff Engineer	Active
Margarita	Karan	SM, Post Market Surveillance	Active
Adam	Kastner	Sr. Sales Representative	Active
Jack	Keiser	Sales Associate	Active
Matthew	Kelleher	Mgr., Post Market Surveillance	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Amber	Kelley	Sales Representative	Active
Amy	Kennedy	Senior Manager, Finance	Active
Samantha	Keough	Commercial Ops Associate	Active
Jacob	Key	Development Engineer	Active
Sherry	Khan	Commercial Ops Specialist	Active
Grayson	Kilburn	Marketing Associate	Active
Michael	Killam	Sr. Sales Representative	Active
Brian	Kim	Sr. Process Eng., Advanced Ops	Active
John	Kish	Supervisor, Machine Shop	Active
Jessi	Kissner	Assoc. Medical Education Mgr.	Active
Edward	Knoll	Sr. Sales Representative	Active
Reese	KOBUROV	Sales Associate	Active
Marta	Koutsogiannis	Staff Qual. Eng., Post Market	Active
Becky	Kovel	Field Count Coordinator II	Active
Scott	Koysh	Sr. Group Manager, Engineering	Active
Caleb	Krantz	Spine Specialist	Active
Madi	Kraus	Commercial Ops Specialist	Active
Dylan	Kressley	Receiving Technician I	Active
John	Kubia	Field Count Coordinator II	Active
Brian	Kunes	Senior Staff Engineer	Active
Katharina	Kuron	Senior Coordinator, QC	Active
Anthony	LaBush	Lead, IT Business Analyst	Active
Dipan	Lad	Principal Sp., R&A	Active
Melissa	Lahman	Finance Lead, Invoicing	Active
Daniel	Laidler	Loaner Technician III	Active
Sydney	Lane	Sr. Sales Representative	Active
Brittany	Lang	Senior Staff Engineer	Active
Brandon	Langley	Demand Planner	Active
Brad	Larson	Sr. Med. Educ. Program Mgr.	Active
Kyle	Layman	Supply Planner	Active
Chad	Lazzell	Quality Control Specialist	Active
Matthew	Leach	Commercial Ops Associate	Active
Alvin	Lee	Lead Data Analyst	Active
Katrina	Lee	Sr. Sales Representative	Active
Beth	Lee	Lead Analyst, PMO	Active
Lee	Levin	Sr. Sales Representative	Active
Xiao	Lin	Sr. Staff Eng., Qual. Assuran.	Active
Draco	Lincoln	Workshop Coordinator	Active
Samiyah	Lincoln	Associate Supervisor, Prod.	Active
Hui	Liu	Principal Microbiologist	Active
Thomas	Livoti III	Inventory Control Tech. II	Active
Sara	Logsdon	Spine Specialist	Active
Silvana	LoNano	Project Manager, QMS	Active
Kennedy	Long	Sr. Sales Representative	Active
Fiorella	Lopardo	Staff Regulatory Affairs Sp.	Active
Laticia	Lopez	Senior Supervisor, Field Ops	Active
Jeferson	Lopez Medina	Field Operations Technician II	Active
Anthony	LoRusso	Sr. Sales Representative	Active
Tia	Lowe	Sr. Spine Specialist	Active
Diana	Luna	Driver	Active
Binh	Luu	Product Packager I	Active
Dung	Luu	Product Packager II	Active
Jeremy	Luu	Sr. Sales Representative	Active
Kyle	Lysek	Field Operations Technician II	Active
Sean	Maag	Sr. Sales Representative	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Thomas	Mackenroth	Sr. Sales Representative	Active
Piotr	Mackowski	Lead Prototype Machinist	Active
Ed	Macy	Sr. Dir., Customer Excellence	Active
Aaron	Madrid	Spine Specialist	Active
Francoise	Makon	Quality Control technician II	Active
Christina	Mangione	Sr. R&A Sp., PMS	Active
Stephen	Marck	Sr. Sales Representative	Active
Mike	Marden	SM, IT Service Delivery	Active
Steven	Marrone	SM, Commercial Analytics	Active
Alexandra	Martin	Sales Associate	Active
Caylin	Martin	Commercial Ops Associate	Active
Emma	Martin	Sales Representative	Active
Jeremy	Martinez	Sales Representative	Active
Drayke	Mash	Team Leader, Production	Active
Nate	Mast	Sr. Sales Representative	Active
Agustin	Mata	Sales Representative	Active
Claire	Mayers	Manager, Quality Assurance	Active
John	Mayor	Vice President, C&E	Active
John	Mazza	Sales Associate	Active
Lawson	McArthur	Sales Associate	Active
Larry	McClintock	Senior Staff Designer	Active
Kaitlin	McClymont	Sr. Staff Eng., Eng.ing	Active
Michael	McCormack	Loaner Technician I	Active
Tyler	McCullough	Fulfillment Technician II	Active
Evelyn	McEnaney	Loaner Technician III	Active
Denise	McIntyre	Finance Specialist, Invoicing	Active
Sydnie	McQueen	Fin. Representative, Invoicing	Active
Jordan	McTeague	Inventory Control Technician I	Active
Brian	Meagher	Sales Representative	Active
Brian	Meerholz	Sales Representative	Active
Komal	Mehta	Sr. Process Dev. Eng. Adv. Ops	Active
Trevor	Melton	Lead Technician, Engineering	Active
Stephanie	Mendez Ramirez	Workshop Coordinator	Active
Nathaniel	Mendoza	Inventory Control Tech. II	Active
Reynaldo	Mendoza	Field Operations Technician II	Active
Andrew	Mermer	Commercial Ops Specialist	Active
Dave	Merritt	Sr. Sales Representative	Active
Jana	Metcalf	Regional Sales Manager	Active
Joseph	Meyer	Staff Engineer	Active
Dmeyler@Gmail	Meyler	Associate General Counsel	Active
Deedee	Michaux	Sr. Sales Representative	Active
Curtiss	Miller	Sr. Staff Eng., Advanced Ops	Active
Daniel	Miller	Sales Representative	Active
Liz	Miller	Development Engineer	Active
Jesse	Miller	Manager, Demand Planning	Active
Robert	Millner	Associate Manager, Sourcing	Active
Sandra	Mills	Finance Specialist, Invoicing	Active
Tyler	MILLS	Team Lead, Field Count	Active
Bryan	Milz	Senior Staff Designer	Active
Alexia	Miquel	Sales Associate	Active
Kara	Miyasato	Sr. Director, Marketing	Active
Aarti	Mohan	Engineering Mgr., Advanced Ops	Active
Nmolina@Vbllc	Molina	Receptionist and Office Manage	Active
Benjamin	MOORE	Sales Representative	Active
Jennifer	Moore	Sr. Manager, Prod. Engineering	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Jesse	Moore	Manager, Intellectual Property	Active
Sarah	Moore	Sr. Med. Educ. Program Mgr.	Active
Brooke	Moran	Commercial Ops Associate	Active
Shraddha	More	Sr. Staff R&A Sp.	Active
Taylor	Moretti Wolfe	Sr. Sales Representative	Active
Randic	Morillo	Sr. Sales Representative	Active
Paige	Morrissey	Sales Representative	Active
William	Mount	Facilities Manager	Active
Steven	Murphy	Program Manager, PMO	Active
Erin	Musau	Portfolio Manager	Active
Madeline	Myers	Sr. Program Mgr. Strat. Mrktg.	Active
Heather	Nafe	Sales Representative	Active
Shawn	Nash	Production Team Leader	Active
Adam	Naymick	Sr. Sales Representative	Active
Peter	Nechvatal	Regional Sales Manager	Active
Dusty	Needham	Chief DPO, Design Controls	Active
Adam	NEITHARDT	Sr. Sales Representative	Active
Geoffrey	Nelson	Regional Sales Manager	Active
Slavka	Nethercott	AM, Quality Management Systems	Active
Dana	Nettles	AM, Med. Affairs, PMS	Active
Hoai	Nguyen	Product Packager I	Active
Bryon	Nicholson	Senior Manager, Sourcing	Active
Lauren	Nitahara	Sr. Staff R&A Sp.	Active
Crystal	Njoku	Quality Control Technician	Active
Michael	Nocera	Spine Specialist	Active
Renee	Norby	Staff Regulatory Affairs Sp.	Active
Taisiya	Novopachennaia	Sr. Staff R&A Sp.	Active
David	Nuckley	SM, R&D Test Engineering	Active
Reece	Nuckols	Sales Associate	Active
Doug	Oakes	Sr. Sales Representative	Active
Todd	Oakes	Sales Representative	Active
Joel	Obiri	Lead Financial Analyst	Active
Maureen	O'Brien	Staff Medical Writer	Active
Alexis	Ocampo	Field Operations Technician I	Active
Leopoldo	Ocampo	Driver	Active
Arnold	Ochoada	Quality Control Tech III	Active
Niall	O'Farrell	Sr Program Manager, PMO	Active
Laurie	Ogden	Senior Analyst, Data Analytics	Active
German	OLIVO-QUEZADA	Driver	Active
Lillian	Olsen	Sr. Director, HR	Active
Josh	Olson	AM, Supply Planning	Active
Siobhan	O'Malley	Sr. R&A Sp., PMS	Active
Jackie	ONeill	Spine Specialist	Active
Javier	Orellana Leon	Associate Supervisor, Prod.	Active
Tim@Vbllc	Ormsby	Associate General Counsel	Active
Max	Ozer	Spine Specialist	Active
Samuel	Painter	Production Team Leader	Active
Erin	Palena	Manager, Advanced Operations	Active
Duncan	Palmer	Manager, PMO & Contin. Improv.	Active
Tee	Pamon JR	Staff Regulatory Affairs Sp.	Active
Nimisha	Pant	Associate PM, Advanced Ops	Active
Karen	Pappas	Finance Specialist, Invoicing	Active
Raffaele	Parisi	Sr. Sales Representative	Active
Andrew	Parker	Quality Control Technician II	Active
Shane	Parkinson	Sr. Sales Representative	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Aakash	Patel	Sales Associate	Active
Nicholas	Pereira	Field Operations Technician II	Active
Corina	perez	Field Operations Technician I	Active
Nicholas	Perez	Loaner Specialist	Active
Andrew	Perkins	Fulfillment Technician III	Active
Jeff	Perlmutter	Area Sales Director	Active
Donna	Perry	AM, Medical Education Support	Active
Matt	Persinger	Machine Shop Team Leader	Active
Toby	Pickens	Sr. Spine Specialist	Active
Manoj	Pillai	Sr. Sales Representative	Active
Ian	Pincus	Sr. Sales Representative	Active
Cynthiaisabel	Pineda Ramos	Inventory Control Tech. II	Active
Lauren	Pinkney	Associate Manager, HRBP	Active
James	Pinto	Regional Sales Manager	Active
Candace	Piper	Lead Sp., Professional Affairs	Active
Andrew	Polyack	Field Scheduler	Active
Spencer	Popejoy	Sr. Staff Engineer	Active
Purna	Prakash	Senior Supply Planner	Active
Abby	Prescott	Sales Associate	Active
David	Pyburn	Sales Representative	Active
Kevin	Quinn	Staff Eng., Process Eng.ing	Active
Michelle	Quinones	Sr. Sp., Professional Affairs	Active
Miguel	Quinones	SA, Financial Controls	Active
Agustin	Quintana	Director, Product Development	Active
Calogero	Ramirez	Staff Engineer, Advanced Ops	Active
Johnathan	Ramirez	Product Packager II	Active
Marci	Ramos	Commercial Ops Associate	Active
Hiral	Rana	Mgr., Integrated Bus. Plan.	Active
Adrian	Razeghi	Financial Analyst	Active
Louis	Redondo	Sr. Sales Representative	Active
Rachel	Rehl	AM, Regulatory Affairs	Active
Kirsten	Reinhold	SM, Regulatory Affairs	Active
Matthew	Remick	Inventory Control Tech. II	Active
Lamia	Reynolds	Loaner Technician I	Active
Tiffany	Riad	Sr. Mgr., Contracts & Pricing	Active
Christina	Rice	Senior Development Engineer	Active
Kate	Richards	Finance AM, Invoicing	Active
Pete	Richter	Manager, IT Business Analysis	Active
Justin	Riley	Sr. Supply Planner	Active
Catherine	Rivera	Senior Ops Quality Analyst	Active
Brendan	Roberts	Sales Associate	Active
Dwight	Roberts II	Workshop Coordinator	Active
Scott	Robinson	SM, Downstream Marketing	Active
Chris	Rodgers	Field Operations Team Leader	Active
Cameron	Rodrigo	Director, Advanced Operations	Active
Eric	RODRIGUEZ	Staff Engineer	Active
Ian	Rodriguez	Commercial Ops Specialist	Active
Megan	Rodriguez	Fin. Representative, Invoicing	Active
Trevor	Roenick	Sr. Sales Representative	Active
Lindsay	Rohr	Senior Manager, Commercial Ops	Active
Raquel	Rojas	Finance Associate, Invoicing	Active
Joseph	Romano	Marketing Communications Lead	Active
Eric	Rooney	AS, Field Operations	Active
Madison	Ross	Lead Strat. Enablement Analyst	Active
Emily	Rossie	AM, Data Analytics	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Lee	Rouss	Commercial Ops Specialist	Active
Kevin	Rowe	Sr. Sales Representative	Active
John	Roy	Sales Representative	Active
Aaron	Rubio	Regional Sales Manager	Active
Evan	Ruggles	Sr. Field Inv. Coordinator	Active
John	Russell	Staff Regulatory Affairs Sp.	Active
Emily	Russo	Senior Portfolio Manager	Active
Dorothy	Rutherford	Set Assembly Technician III	Active
Marcus	Rutherford	Reverse Logistics Tech. III	Active
Anthony	Ryan	Senior Staff Engineer	Active
Jason	Ryznar	Sr. Sales Representative	Active
Samuel	Saavedra	Contract Activation Analyst	Active
Carlota	Sagarduy	Intern, Engineering	Active
Krystal	San Miguel	Associate Supervisor, Finance	Active
Jessica	Sanchez	Assoc. Manager, Advanced Ops	Active
Ralph	Santa Ana	Driver	Active
Blas	Santiago	Field Operations Team Lead	Active
Adrienne	Saraceni	Dir., Qual. Management Systems	Active
Jennifer	Sayama	Lead Analyst, Sales Operations	Active
Korie	Schmidt	Field Scheduler	Active
Laura	Scholl	Principal R&A Sp.	Active
Tyler	Schwarz	Sales Associate	Active
Sara	Schweitzer	Lead TA Business Partner	Active
Gail	Scott	Quality Control Technician III	Active
Hadley	Scott	Project Manager, PMO	Active
Jahsee	Sele	Product Packager I	Active
Wannie	Sele	Production Team Lead	Active
William	Sele	Quality Control Technician III	Active
Benjamin	Shafer	SM, Supply Planning	Active
Hetal	Shah	Lead Rebate Analyst	Active
Ali	Sharifi-Mehr	Chief Engineer	Active
Marc	Shea II	Reverse Logistics Tech. III	Active
Kim	Shebest	Executive Assistant	Active
William	Sheehan	Regional Sales Manager	Active
James	Sherman	Regional Sales Manager	Active
Robert	Simpson	Sales Associate	Active
Travis	Sines	Loaner Technician II	Active
Neeta	Singh	Senior Marketing Associate	Active
Margaret	Smarzewski	Sales Education Training Mgr.	Active
Jolanda	Smedley	Senior Field Count Associate	Active
Cristy	Smith	Employee and CEL	Active
Daniel	Smith	Loaner Specialist	Active
Katie	Smith	Inventory Control Tech. II	Active
Samantha	Smith	Quality Engineer, Post Market	Active
Chip	Smith JR	Regional Sales Manager	Active
Damian	Sobrevilla	Senior Staff Engineer	Active
Megan	Sochanski	Sr. Eng., PMS	Active
Zinoviy	Sosnov	Lead Prototype Machinist	Active
Daniel	Spang	Sr. Sales Representative	Active
Michael	Spies	Associate Manager, R&D	Active
James	Stapleton	Field Operations Team Leader	Active
King	Starks II	Senior Supervisor, Field Count	Active
Jeremiah	Staubs	Senior Process Improvement Sp.	Active
Brent	Steele	Sr. Sales Representative	Active
Barry	Stein	Sr. Sales Representative	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Tyler	Stevens	Sales Representative	Active
Jakob	Stevenson	Sr. Process Dev. Eng. Adv. Ops	Active
Lauren	Stewart-Ebert	Staff Medical Writer	Active
Adrienne	Stone	Lead QC Coordinator	Active
Diana	Stonehouse	Receptionist CE Coordinator	Active
Nathan	Stotts	Area Vice President	Active
Sarah	Stover	Sales Associate	Active
Daniel	Strancar	Sales Associate	Active
Colleen	Sullivan	Dir., Market Int. & Strat.	Active
Mary	Sullivan	Senior Operations Coordinator	Active
Mclain	Sullivan	Inventory Control Tech. II	Active
Annie	Sun	Product Packager III	Active
Margo	Suryanaga	AM, Data Science & Engineering	Active
Sandra	Suryanto	Finance Associate, Invoicing	Active
Teddy	Sweeney	Sr. Sales Representative	Active
Shea	Sweeney	Director, Integrated Planning	Active
Mark	SWISHER	Sales Representative	Active
Sheraz	Tariq	Sr. Proj. Mgr. New Prod. Dev.	Active
Daniel	Tavani	Director, Business Transform.	Active
Diana	Tavenner	Quality Control Technician II	Active
Brian	Taylor	Sr. Sales Representative	Active
Jake	Taylor	Sales Representative	Active
Nico	TAYLOR	Sales Associate	Active
Olivia	Taylor	Sales Representative	Active
Valerie	Tighe	Staff Engineer	Active
Price	Timmerman IV	Sr. Sales Representative	Active
Jared	Tiso	Sr. Spine Specialist	Active
Brian	Tomasello	Sr. Spine Specialist	Active
Matt	Tomasello	Sr. Sales Representative	Active
Jose	Torres	Sales Representative	Active
Chris	Tortora	Sr. Director, Qual. Assurance	Active
Terrence	Tracey JR	Sr. Sales Representative	Active
Gervin	Trejos	Driver	Active
Andrew	Trione	Lead Analyst, Finance	Active
Ray	Tsang	Staff Quality Engineer	Active
Dreyfus	Tuazon	Product Packaging Specialist	Active
Joshua	Tuparan	Loaner Specialist	Active
Annemarie	Valentine	Workshop Coordinator	Active
Gina	Van Natten	Principal Marketing Manager	Active
Blair	van't Hoff	Spine Specialist	Active
Andrea	Vargas-Mark	Manager, PMO	Active
Rene	Vega II	Sr. Sales Representative	Active
Todd	Venema	Sales Associate	Active
Kevin	Vergara	Commercial Ops Associate	Active
Noelle	Verhoog	Senior Quality System Sp.	Active
Alysse	Vindeed	Staff R&A Sp., PMS	Active
Justice	Virbalis	Team Member, Driver	Active
Jake	Vitulli	Lead Field Inv. Coordinator	Active
Simona	Voic	Program Director, R&A	Active
Cole	VonHandorf	Sales Associate	Active
Amanda	Wacaster	Finance Associate, Invoicing	Active
Sandra	Walker	Associate Supervisor, Finance	Active
Shaun	Walker SR	Sr. Field Inv. Coordinator	Active
Katie	Walko	Staff Regulatory Affairs Sp.	Active
Stuart	Wallace	Clinical Project Manager	Active

First Name	Last Name	Business Title	Employee Status Descr Long
Windell	Wallace	Lead Field Inv. Coordinator	Active
Joe	Walsh	Inventory Control Specialist	Active
James	WALSH JR	Loaner Technician III	Active
Kathryn	Ward	Sr. Staff Qual. Eng., NC/CAPA	Active
Jeff	Webb	Sr. Sales Representative	Active
Zachary	Weglos	Sales Representative	Active
Jason	Weinrich	Sr. Spine Specialist	Active
Caroline	Weir	Program Mgr., Commercial Ops	Active
Stephen	Welkie	Sr. Sales Representative	Active
James	White	Sales Associate	Active
Matt	White	Sr. Sales Representative	Active
Joshua	Wholters	Commercial Ops Specialist	Active
Lauren	Wilch	Sr. Advanced Quality Engineer,	Active
Sean	wilinski	CNC Programmer/Machinist	Active
Ingrid	Wilkins	Manager, Field Inventory	Active
Brendan	Willard	Sr. Sales Representative	Active
Jon	Willard	Manager, Quality Assurance	Active
Jennifer	Wilson	Finance Associate, Invoicing	Active
Joan	Wilson	Sr. Sales Representative	Active
Kim	Winkler	Manager, HRBP	Active
Dustin	Winship	Sr. Sales Representative	Active
James	Wright	Commercial Ops Associate	Active
Kate	Wright	Bioskills Lab Assistant	Active
Max	Wright	Sr. Sales Representative	Active
Chase	Yearty	Sales Associate	Active
Emily	Young	Senior Lead Data Analyst	Active
Mike	Young	Regional Sales Manager	Active
Deann	Zamosky	Sr. Spine Specialist	Active
Mark	Zellers	Quality System Associate	Active
Noah	Zellers	Senior Data Engineer	Active
Loutie	Zerbo	Loaner Technician III	Active
Carolyn	Zineddin	PMS Coodinator	Active

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	38-1239739
(State of incorporation)	(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan	49002
(Address of principal executive offices)	(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange
3.375% Notes due 2032	SYK32	New York Stock Exchange
3.625% Notes due 2036	SYK36	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $123,147,898,554 at June 30, 2024. There were 381,579,123 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2025 Annual Meeting of Shareholders (the 2025 proxy statement) are incorporated by reference into Part III.

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PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers,
we are driven
to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right.	We do what we say.	We grow talent.	We deliver.

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and artificial intelligence-assisted virtual care platform technology; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics and Spine, the Interventional Spine (IVS) portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. In addition, we changed the name of our "Orthopaedics and Spine" operating segment to "Orthopaedics."

Quarterly Net Sales - Enabling Technologies

	2024	2023	2022
Mar 31	$ 30	$ 31	$ 30
Jun 30	$ 31	$ 32	$ 25
Sep 30	$ 59	$ 54	$ 44
Dec 31	$ 32	$ 32	$ 32
Total	**$ 152**	**$ 149**	**$ 131**

Quarterly Net Sales - IVS

	2024	2023	2022
Mar 31	$ 98	$ 77	$ 65
Jun 30	$ 98	$ 83	$ 73
Sep 30	$ 117	$ 84	$ 72
Dec 31	$ 100	$ 83	$ 72
Total	**$ 413**	**$ 327**	**$ 282**

Quarterly Net Sales - Spinal Implants

	2024	2023	2022
Mar 31	$ 171	$ 176	$ 183
Jun 30	$ 178	$ 181	$ 193
Sep 30	$ 186	$ 180	$ 182
Dec 31	$ 172	$ 176	$ 175
Total	**$ 707**	**$ 713**	**$ 733**

Net Sales by Reportable Segment

	2024		2023		2022	
MedSurg and Neurotechnology	$ 13,518	60 %	$ 12,163	59 %	$ 10,893	59 %
Orthopaedics	9,077	40	8,335	41	7,556	41
Total	**$ 22,595**	**100 %**	**$ 20,498**	**100 %**	**$ 18,449**	**100 %**

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and artificial intelligence-assisted virtual care platform technology (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson MedTech (a subsidiary of Johnson & Johnson) and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson Medtech, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2024		2023		2022	
Instruments	$ 2,834	21 %	$ 2,534	21 %	$ 2,245	21 %
Endoscopy	3,389	25	3,068	25	2,759	25
Medical	3,852	28	3,459	28	3,031	28
Neurovascular	1,307	10	1,226	11	1,200	11
Neuro Cranial	2,136	16	1,876	15	1,658	15
Total	$ 13,518	100 %	$ 12,163	100 %	$ 10,893	100 %

In 2024 Instruments launched SurgiCount+ powered by Triton, which combines our existing sponge counting technology with artificial intelligence and quantifying blood loss software. We also launched CoPilot, which combines with our Spine Q guidance system to help surgeons plan and perform certain spinal procedures, including supporting bone resection, pedicle preparation and screw delivery.

In addition we completed the acquisition of Vertos Medical, Inc., a leader in interventional pain management solutions for chronic lower back pain caused by lumbar spinal stenosis. The acquisition of Vertos is complementary to our Interventional Spine business as we continue to focus on advanced pain procedures.

Endoscopy continued to deliver its 4K 1788 Camera platform to the market. Our 1788 Camera platform features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat and can be used to visualize indocyanine green and Cytalux.

Medical launched the LIFEPAK 35 monitor/defibrillator, our next generation platform designed to optimize care with new clinical features such as the new Glasgow 30.4 algorithm, cprINSIGHT, 15-lead monitoring capabilities, and STJ insight and mapping. LIFEPAK 35 combines a modern intuitive touch screen display and increased processing power with Bluetooth and WiFi data connectivity.

Medical also completed the acquisition of care.ai, a virtual care and ambient intelligence solutions platform. care.ai adds complementary technology that is expected to integrate seamlessly with the Vocera platform (Vocera) and Stryker's devices, providing customers with an enterprise-wide ecosystem that is intended to deliver dynamic clinical workflows and further the development of smart care facilities.

Neurovascular initiated a targeted launch of the Surpass Elite Flow Diverting Stent (FDS) in the U.S. and South Korea. Surpass Elite FDS is designed to reduce thrombin generation when compared to unmodified stents. Additionally, Neurovascular launched Surpass Evolve FDS in Japan. The Stryker FDS platform is designed to effectively treat aneurysms by redirecting blood flow away from the aneurysm to promote healing.

Orthopaedics

Orthopaedics products primarily include implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technologies, products and services they need to support each patient's clinical challenge.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, Johnson & Johnson MedTech and Smith & Nephew.

Composition of Orthopaedics Net Sales

	2024		2023		2022	
Knees	$ 2,447	27 %	$ 2,273	27 %	$ 1,997	26 %
Hips	1,704	19	1,544	18	1,413	19
Trauma and Extremities	3,507	39	3,147	38	2,807	37
Spinal Implants	707	8	713	9	733	10
Other	712	8	658	8	606	8
Total	$ 9,077	100 %	$ 8,335	100 %	$ 7,556	100 %

In 2024 we continued the full commercial launch of our Triathlon Hinge revision knee system. Triathlon Hinge received approval in August of 2023 and is now released in the U.S., Canada and New Zealand. We also continued delivering growth in total hip arthroplasty, particularly in the primary segment where Direct Anterior Reconstructive Technology and Mako Total Hip can help to reduce, if not eliminate, a surgeon's use of intraoperative fluoroscopy during direct anterior hip procedures. With the acquisition of SERF SAS, we strengthened distribution in key European markets and continue to scale differentiated solutions such as the Novae monolithic dual mobility cup engineered to deliver greater hip stability and reduce dislocation risk.

We continued to expand our global footprint of Mako SmartRobotics™ in 2024 which is now sold in more than 45 countries. To date more than one million robotic Mako Total Knees and 1.5 million robotic procedures across Total Hips, Total Knees and Partial Knees have been performed globally. Stryker's Joint Replacement division also launched the "Scan. Plan. Mako Can." direct to patient campaign, accelerating awareness of Mako technology in the U.S.

Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

In December 2024 we performed our first Mako Shoulder procedure using robotic-arm assistance to remove bone, prepare the glenoid surface and enable positioning and placement of the Perform Reversed Glenoid implant.

In 2024 Trauma launched Pangea, a comprehensive variable angle plating portfolio designed to optimize plate fit to bone utilizing simple, intuitive instrumentation that enhances ease of use and reproducibility. These combined solutions empower Stryker to deliver a complete portfolio across all trauma segments.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2024 we owned approximately 5,600 United States patents and approximately 8,600 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the

summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2022, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. Any resulting investigations and prosecutions potentially carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2024 we had approximately 53,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups, which are open to all employees, to focus on creating community and belonging

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer to our executive officers.

Information about our Executive Officers

As of January 31, 2025

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	59	Chair, Chief Executive Officer and President	2011
Yin C. Becker	61	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	59	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	63	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	55	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	54	Vice President, Chief Legal Officer	2019
Viju S. Menon	57	Group President, Global Quality and Operations	2018
J. Andrew Pierce	51	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	48	Group President, Orthopaedics	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2025 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our or Inari Medical, Inc.'s ("Inari") products;
- geopolitical risks, including from international conflicts, which could, among other things, lead to increased market volatility;

- pricing pressures generally, including cost-containment measures that have adversely affected and could in the future adversely affect the price of or demand for our or Inari's products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products, including Inari products, by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in coverage and reimbursement levels from third-party payors;
- changes in the competitive environment;
- breaches, failures or other disruptions of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes, including our acquisition of Inari;
- our ability to realize any anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- uncertainties as to the timing of the tender offer for shares of Inari common stock and the subsequent merger with Inari;
- uncertainties as to how many of Inari's stockholders will tender their shares in the tender offer;
- the failure to satisfy any of the closing conditions to the acquisition of Inari, including the expiration or termination of the Hart-Scott-Rodino Antitrust Improvements Act waiting period (and the risk that such governmental approval may result in the imposition of conditions that could adversely affect the expected benefits of the transaction);
- delays in consummating the acquisition of Inari or the risk that the transaction may not close at all;
- unexpected liabilities, costs, charges or expenses in connection with the acquisition of Inari;
- the effects of the proposed Inari transaction (or the announcement thereof) on the parties' relationships with employees, customers, other business partners or governmental entities; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to the risk of product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to any raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to, among other things, the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, business disruptions, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer, possibly materially. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, in recent years, the market has experienced inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may in the future result in, high interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may in the future experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, high interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors, including changes in reimbursement practices and coverage policies and third-party payor cost containment measures: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in coverage or reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. Coverage policies and reimbursement levels can vary across the payer community globally, regionally, and locally, and may affect which products customers purchase, the market acceptance rate for new technologies and the prices customers are willing to pay for those products in a particular jurisdiction. Furthermore, any changes to the coverage or reimbursement landscape, or adverse decisions relating to our products by administrators of these systems could significantly reduce reimbursement for procedures using our products or result in denial of reimbursement for those products, which could adversely affect customer demand, or the price customers are willing to pay for such products. Public and private payers have challenged, and are expected to continue to challenge, prices charged for medical products and services. Such downward pricing pressures from any or all of these payers may result in an adverse effect on our business, results of operations, financial condition and cash flows. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition and the regulatory burden in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation, new product development and improvement of existing products. New business models, products and surgical procedures, as well as improvements to existing products, are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, including by our existing competitors and new market entrants, which could adversely impact demand for certain of our existing products. The success of our products and services depends on, among other things, our ability to properly identify customer needs and predict future needs; innovate and develop new technologies, services and applications at an accelerated pace; and appropriately allocate our research and development spending to products and services with higher growth. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We work with healthcare professionals in a transparent and responsible manner and seek to maintain these relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in coverage or reimbursement levels from third-party payors in the United States and other countries; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with

the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability and uncertainty; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which has increased the risks we are subject to.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Furthermore, numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Emerging technologies such as generative artificial intelligence (AI) may be used by malicious actors to create more targeted phishing narratives, spread disinformation about us or our products or otherwise strengthen social engineering capabilities. Some of our products, services, and information technology systems contain or use open-source software which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, unauthorized access to, and disruptions of, products or systems. While such breaches, unauthorized access and disruptions have not had a material effect on us to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity or other technology related incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment and customer requirements related to information security, data collection and use, and privacy become increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability.

Hardware and software failures or delays in our key information technology systems, networks, processes or sites could disrupt our operations, cause the loss of confidential information or otherwise adversely impact our business. Our systems, networks, processes and sites may be vulnerable to damage, disruptions and shutdown from a variety of sources, including malfunctions in maintenance updates or security patches, design defects, the age of the technology, network failures, modernization or other initiatives, human acts and natural disasters. For example, some of our information technology systems contain legacy third-party software components for which we depend on a layered security

approach to protect against exploitation, which may not be effective. Any such damage or disruptions could also compromise the security of our information systems and networks. These issues can also arise as a result of failures by, or in the software or hardware of, third parties, including networks or service providers, with whom we do business and over whom we have limited or no control. Any disruption or failure of our systems, networks, processes or sites could have a material impact on our business and operations.

If our IT systems, networks or processes are damaged or cease to function properly for any reason, the networks, service providers, hardware or software we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive workforce in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by

governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. It is not possible to predict whether elective medical procedures will be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and may continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm, among other things.

Our use of AI and other emerging technologies could adversely impact our business and financial results: We have begun to deploy AI and other emerging technologies in various facets of our operations and we continue to explore further use cases. The rapid advancement of these technologies presents opportunities for us in research, manufacturing, commercialization, and other business endeavors, but also entails risks, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. In addition, any disruption or failure in the AI functionality we incorporate into our business activities, products or services could adversely impact our business or result in delays or errors in our product offerings. The legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity and privacy and data protection. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant costs on us and limit our ability to effectively develop, deploy or use AI technologies. Furthermore, if we are unable to effectively manage the use of AI technologies by our employees and service providers, our confidential information, intellectual property and reputation could be put at risk. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with prior pandemics, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks that revise the existing profit allocation and nexus rules (Pillar 1) and ensure a minimal level of taxation (Pillar 2), respectively. In 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws are effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes, could increase tax expense in future periods.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to healthcare or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. Both in the U.S. and internationally, governmental authorities may make legislative or administrative reforms to existing reimbursement programs, make adverse decisions relating to our

products' coverage or reimbursement, or make changes to patient access to healthcare, all of which could adversely impact the demand for and usage of our products or the prices that our customers are willing to pay for them. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. For example, governmental authorities in the United States and internationally have or are considering adopting regulations on the use of per- and polyfluoroalkyl substances. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We may also be subject to legal obligations in some countries that require disclosure or sharing of proprietary information. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws have in the past resulted and could in the future result in investigations, litigation or government proceedings, and we have been and may in the future be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. For example, in 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and enforcement and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial

Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive) mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The European Product Liability Directive was revised in 2024 and will become fully adopted into each member state's national laws by 2026. The revised Product Liability Directive and Collective Redress Directive exposes us to additional litigation risks and could result in significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on intellectual proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents and the expiration of patents may lead to a loss of exclusive rights and/or increased competition.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties, financing transactions in currencies other than the United States Dollar and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars. In recent years, currency exchange rates have been especially volatile, and these currency fluctuations have affected, and may continue to affect, our results of operations.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve, including in diverging directions. On occasion, we announce new initiatives and make disclosures, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest and applicable regulatory requirements, which include environment and sustainability, workforce-related issues, diversity, equity and inclusion and supply chain management, among others. Implementation of these initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in, among other things, reduced demand for our products, reduced profits, increased investigations and litigation and an increased risk of reputational damage. If we are unable to satisfy evolving criteria, certain investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate or undesirable. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change have increased and are expected to further increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures and flooding, which could cause more significant business and supply chain

interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors periodically. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 27 company-owned and 297 leased locations worldwide including 45 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products.

We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various ongoing proceedings, legal actions and claims arising in the normal course of our business, including proceedings related to product, labor, intellectual property and other matters. Refer to Note 7 to our Consolidated Financial Statements for further information.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2025 there were 2,510 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2024 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2024 was $1,033.

In the fourth quarter 2024 we did not issue shares of our common stock as performance incentive awards to employees. When issued, these shares are not registered under the Securities Act of 1933 based on the conclusion that the awards are not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2019 in our common stock and each of the indices.



Company / Index	2019	2020	2021	2022	2023	2024
Stryker Corporation	**$ 100.00**	**$ 118.17**	**$ 130.25**	**$ 120.59**	**$ 149.29**	**$ 181.15**
S&P 500 Index	$ 100.00	$ 118.40	$ 152.39	$ 124.79	$ 157.59	$ 197.02
S&P 500 Health Care Index	**$ 100.00**	**$ 113.45**	**$ 143.09**	**$ 140.29**	**$ 143.18**	**$ 146.67**

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2024	2023	2022	2021	2020
Net sales	$ 22,595	$ 20,498	$ 18,449	$ 17,108	$ 14,351
Cost of sales	8,155	7,440	6,871	6,140	5,294
Gross profit	$ 14,440	$ 13,058	$ 11,578	$ 10,968	$ 9,057
Research, development and engineering expenses	1,466	1,388	1,454	1,235	984
Selling, general and administrative expenses	7,685	7,111	6,386	6,266	5,163
Amortization of intangible assets	623	635	627	619	472
Goodwill and other impairments	977	36	270	264	215
Total operating expenses	$ 10,751	$ 9,170	$ 8,737	$ 8,384	$ 6,834
Operating income	$ 3,689	$ 3,888	$ 2,841	$ 2,584	$ 2,223
Other income (expense), net	(197)	(215)	(158)	(303)	(269)
Earnings before income taxes	$ 3,492	$ 3,673	$ 2,683	$ 2,281	$ 1,954
Income taxes	499	508	325	287	355
Net earnings	$ 2,993	$ 3,165	$ 2,358	$ 1,994	$ 1,599
Net earnings per share of common stock:					
Basic	$ 7.86	$ 8.34	$ 6.23	$ 5.29	$ 4.26
Diluted	$ 7.76	$ 8.25	$ 6.17	$ 5.21	$ 4.20
Dividends declared per share of common stock	$ 3.240	$ 3.050	$ 2.835	$ 2.585	$ 2.355
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,743	$ 3,053	$ 1,928	$ 3,019	$ 3,024
Accounts receivable, net	3,987	3,765	3,565	3,022	2,701
Inventories	4,774	4,843	3,995	3,314	3,494
Property, plant and equipment, net	3,448	3,215	2,970	2,833	2,752
Total assets	$ 42,971	$ 39,912	$ 36,884	$ 34,631	$ 34,330
Accounts payable	1,679	1,517	1,413	1,129	810
Total debt	13,597	12,995	13,048	12,479	13,991
Shareholders' equity	$ 20,634	$ 18,593	$ 16,616	$ 14,877	$ 13,084
Cash Flow Data					
Net cash provided by operating activities	$ 4,242	$ 3,711	$ 2,624	$ 3,263	$ 3,277
Purchases of property, plant and equipment	755	575	588	525	487
Depreciation	427	393	371	371	340
Acquisitions, net of cash acquired	1,628	390	2,563	339	4,222
Amortization of intangible assets	623	635	627	619	472
Payments of dividends	1,219	1,139	1,051	950	863
Repurchase of common stock	—	—	—	—	—
Other Data					
Number of shareholders of record	2,520	2,518	2,533	2,551	2,597
Approximate number of employees	53,000	52,000	51,000	46,000	43,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Overview of 2024

In 2024 we achieved reported net sales growth of 10.2%. Excluding the impact of acquisitions and divestitures, sales grew 10.2% in constant currency. We reported net earnings of $2,993 and net earnings per diluted share of $7.76. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,700 and adjusted net earnings per diluted share[1] of $12.19 representing growth of 15.0%.

We continued our capital allocation strategy by investing $1,628 in acquisitions and paying $1,219 in dividends to our shareholders.

In 2024 we completed various acquisitions for total consideration of $1,628 in upfront payments, net of cash acquired, as well as $400 of contingent consideration if certain commercial or clinical milestones are achieved. Refer to Note 6 to our Consolidated Financial Statements for further information.

In May 2024 we repaid the outstanding $600 principal amount of the 3.375% senior unsecured notes due May 15, 2024. In September 2024 we issued $750 of 4.250% senior unsecured notes due September 11, 2029, €800 of 3.375% senior unsecured notes due September 11, 2032, $750 of 4.625% senior unsecured notes due September 11, 2034 and €600 of 3.625% senior unsecured notes due September 11, 2036. In November 2024 we repaid the outstanding €500 of floating rate senior notes and in December 2024 we repaid €850 of 0.250% senior unsecured notes.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

	2024	2023	2022	Percent Net Sales 2024	Percent Net Sales 2023	Percent Net Sales 2022	Percentage Change 2024 vs. 2023	Percentage Change 2023 vs. 2022
Net sales	$ 22,595	$ 20,498	$ 18,449	100.0 %	100.0 %	100.0 %	10.2 %	11.1 %
Gross profit	14,440	13,058	11,578	63.9	63.7	62.8	10.6	12.8
Research, development and engineering expenses	1,466	1,388	1,454	6.5	6.8	7.9	5.6	(4.5)
Selling, general and administrative expenses	7,685	7,111	6,386	34.0	34.7	34.6	8.1	11.4
Amortization of intangible assets	623	635	627	2.8	3.1	3.4	(1.9)	1.3
Goodwill and other impairments	977	36	270	4.3	0.2	1.5	nm	nm
Other income (expense), net	(197)	(215)	(158)	(0.9)	(1.0)	(0.9)	(8.4)	36.1
Income taxes	499	508	325	nm	nm	nm	(1.8)	56.3
Net earnings	$ 2,993	$ 3,165	$ 2,358	13.2 %	15.4 %	12.8 %	(5.4)%	34.2 %
Net earnings per diluted share	$ 7.76	$ 8.25	$ 6.17				(5.9)%	33.7 %
Adjusted net earnings per diluted share[1]	$ 12.19	$ 10.60	$ 9.34				15.0 %	13.5 %

nm - not meaningful

Geographic and Segment Net Sales

	2024	2023	2022	Percentage Change 2024 vs. 2023 As Reported	Percentage Change 2024 vs. 2023 Constant Currency	Percentage Change 2023 vs. 2022 As Reported	Percentage Change 2023 vs. 2022 Constant Currency
Geographic:							
United States	$ 16,943	$ 15,257	$ 13,638	11.0 %	11.0 %	11.9 %	11.9 %
International	5,652	5,241	4,811	7.9	9.8	8.9	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %
Segment:							
MedSurg and Neurotechnology	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	11.7 %	12.2 %
Orthopaedics	9,077	8,335	7,556	8.9	9.4	10.3	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %

Supplemental Net Sales Growth Information

				Percentage Change									
				2024 vs. 2023					2023 vs. 2022				
						United States	International				United States	International	
	2024	2023	2022	As Reported	Constant Currency	As Reported	As Reported	Constant Currency	As Reported	Constant Currency	As Reported	As Reported	Constant Currency
MedSurg and Neurotechnology:													
Instruments	$ 2,834	$ 2,534	$ 2,245	11.9 %	12.1 %	12.5 %	9.5 %	10.6 %	12.9 %	13.0 %	13.5 %	10.4 %	11.8 %
Endoscopy	3,389	3,068	2,759	10.5	11.0	11.1	7.7	10.7	11.2	11.7	11.9	8.0	9.9
Medical	3,852	3,459	3,031	11.4	11.7	14.6	(2.0)	(0.3)	14.1	14.4	15.0	10.7	12.3
Neurovascular	1,307	1,226	1,200	6.6	8.2	4.7	7.9	10.5	2.2	4.0	8.3	(1.5)	1.5
Neuro Cranial	2,136	1,876	1,658	13.9	14.1	15.0	8.7	10.2	13.1	13.4	12.7	15.4	16.8
	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	12.7 %	5.9 %	7.9 %	11.7 %	12.2 %	13.1 %	7.2 %	9.2 %
Orthopaedics:													
Knees	$ 2,447	$ 2,273	$ 1,897	7.6 %	8.2 %	6.7 %	10.4 %	12.2 %	13.8 %	14.4 %	12.3 %	18.5 %	20.9 %
Hips	1,704	1,544	1,413	10.3	11.3	7.2	15.9	18.4	9.3	10.4	10.3	7.5	10.7
Trauma and Extremities	3,507	3,147	2,807	11.4	11.6	12.6	8.3	9.1	12.1	12.2	12.9	10.1	10.5
Spinal Implants	707	713	733	(0.7)	(0.3)	(2.1)	2.5	3.8	(2.7)	(2.0)	(2.2)	(4.1)	(3.4)
Other	712	658	606	8.1	9.6	7.3	10.1	15.4	8.6	9.5	2.9	25.8	32.3
	$ 9,077	$ 8,335	$ 7,556	8.9 %	9.4 %	8.4 %	10.2 %	12.0 %	10.3 %	10.9 %	10.0 %	11.1 %	13.1 %
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.0 %	7.9 %	9.8 %	11.1 %	11.6 %	11.9 %	8.9 %	10.9 %

Note: In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics, the interventional spine portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. Neuro Cranial includes sales related to interventional spine of $413, $327 and $282 for 2024, 2023 and 2022. Other Orthopaedics includes sales related to Enabling Technologies of $152, $149 and $131 for 2024, 2023 and 2022. In the first quarter 2024 a product line previously included in Instruments has been reclassified to Endoscopy to align with a change in our internal reporting structure. We have reflected these changes in all historical periods presented.

Consolidated Net Sales

Consolidated net sales in 2024 increased 10.2% as reported and 10.7% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.5% impact of acquisitions and divestitures, net sales in constant currency increased by 9.1% from increased unit volume and 1.1% due to higher prices. The unit volume increase was primarily due to higher shipments across all businesses.

Consolidated net sales in 2023 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 10.9% from increased unit volume and 0.6% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses and most Orthopaedics businesses.

MedSurg and Neurotechnology Net Sales

MedSurg and Neurotechnology net sales in 2024 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.4% impact of acquisitions and divestitures, net sales in constant currency increased by 9.5% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

MedSurg and Neurotechnology net sales in 2023 increased 11.7% as reported and 12.2% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.3% impact of acquisitions and divestitures, net sales in constant currency increased by 10.2% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

Orthopaedics Net Sales

Orthopaedics net sales in 2024 increased 8.9% as reported and 9.4% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.7% impact of acquisitions and divestitures, net sales in constant currency increased by 8.7% from increased unit volume. The unit volume increase was due to higher shipments across all Orthopaedics businesses.

Orthopaedics net sales in 2023 increased 10.3% as reported and 10.9% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.6%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 11.9% from increased unit volume partially offset by 1.1% due to lower prices. The unit volume increase was due to higher shipments across most Orthopaedics businesses.

Gross Profit

Gross profit was $14,440, $13,058 and $11,578 in 2024, 2023, and 2022. The key components of the change were:

	Gross Profit Percent Net Sales
2022	**62.8 %**
Sales pricing	20 bps
Volume and mix	100 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	10 bps
2023	**63.7 %**
Sales pricing	40 bps
Volume and mix	60 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	(20) bps
Structural optimization and other special charges	(20) bps
2024	**63.9 %**

Gross profit as a percentage of net sales increased to 63.9% in 2024 from 63.7% in 2023 due to higher sales pricing and favorable volume partially offset by higher manufacturing and supply chain costs primarily due to inflationary pressures impacting fixed and variable manufacturing costs as well as higher amortization of inventory stepped up to fair value.

Gross profit as a percentage of net sales increased to 63.7% in 2023 from 62.8% in 2022 due to higher sales pricing and favorable volume offset by higher manufacturing and supply chain costs primarily due to higher raw material costs in the first six months of 2023 and supply chain inefficiencies.

While segment mix was not a significant driver of the change in gross profit as a percent of net sales between 2024, 2023 and 2022, we generally expect segment mix to have an unfavorable impact for the foreseeable future as we anticipate more rapid sales growth in our lower gross margin MedSurg and Neurotechnology segment than our Orthopaedics segment.

Research, Development and Engineering Expenses

Research, development and engineering expenses as a percentage of net sales in 2024 decreased to 6.5% from 6.8% in 2023 primarily due to lower spend on medical device regulations in the European Union.

Research, development and engineering expenses as a percentage of net sales in 2023 decreased to 6.8% from 7.9% in 2022 primarily due to increased spending for product launches, the write-off of certain intangible assets and higher spend related to the new medical device regulations in the European Union in 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses as a percentage of net sales in 2024 decreased to 34.0% from 34.7% in 2023 primarily due to continued spend discipline and lower charges for structural optimization and certain legal matters partially offset by higher acquisition-related costs.

Selling, general and administrative expenses as a percentage of net sales in 2023 of 34.7% remained relatively flat with 34.6% in 2022 as charges of $132 related to share-based awards for Vocera employees that vested upon our acquisition in 2022 were partially offset by disciplined increases in spend and investments in 2023 to support our growth, including sales growth incentives and increased spend on travel and meetings. In addition, in 2022 we determined that certain commercial and regulatory milestones related to technology acquired in the purchase of Mobius Imaging and Cardan Robotics were no longer probable of being achieved and recorded $110 to reduce the fair value of contingent consideration.

Amortization of Intangible Assets

Amortization of intangible assets was $623, $635 and $627 in 2024, 2023 and 2022. These amounts include amortization related to intangible assets acquired in 2024 from various acquisitions, 2023 from Cerus Endovascular Limited (Cerus) and 2022 from Vocera. Refer to Notes 6 and 8 to our Consolidated Financial Statements for further information.

Goodwill and Other Impairments

In 2024 and 2022 we recorded goodwill impairment charges of $456 and $216 related to our Spine business.

In 2024 we recognized an estimated loss of $362 as a result of classifying certain assets in our Spinal Implants business as held for sale. Refer to Notes 8, 16 and 17 to our Consolidated Financial Statements for further information.

In 2024, 2023 and 2022 we recorded other impairments of $159, $36 and $54. Refer to Notes 15 and 16 to our Consolidated Financial Statements for further information.

Operating Income

Operating income was $3,689, $3,888 and $2,841 in 2024, 2023 and 2022. Operating income decreased as a percentage of sales to 16.3% in 2024 from 19.0% in 2023 and increased from 15.4% in 2022. Refer to the comments above for discussion of the primary drivers of the change.

MedSurg and Neurotechnology operating income as a percentage of net sales increased to 29.6% in 2024 from 28.5% in 2023. MedSurg and Neurotechnology operating income as a percentage of net sales increased to 28.5% in 2023 from 26.0% in 2022. Orthopaedics operating income as a percentage of net sales increased to 28.5% in 2024 from 27.2% in 2023. Orthopaedics operating income as a percentage of net sales increased to 27.2% in 2023 from 29.1% in 2022. The key components of the change were:

	Operating Income Percent Net Sales	
	MedSurg and Neurotechnology	Orthopaedics
2022	**26.0 %**	**29.1 %**
Sales pricing	70 bps	(30) bps
Volume	100 bps	80 bps
Manufacturing and supply chain costs	90 bps	(220) bps
Research, development and engineering expenses	50 bps	20 bps
Selling, general and administrative expenses	(60) bps	(40) bps
2023	**28.5 %**	**27.2 %**
Sales pricing	70 bps	0 bps
Volume	40 bps	70 bps
Manufacturing and supply chain costs	(40) bps	(20) bps
Research, development and engineering expenses	0 bps	10 bps
Selling, general and administrative expenses	40 bps	70 bps
2024	**29.6 %**	**28.5 %**

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2024 from 2023 was primarily driven by higher unit volumes, higher prices and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2023 from 2022 was primarily driven by higher unit volumes, higher prices and lower manufacturing and supply chain costs due to supply chain challenges impacting capital products in our MedSurg businesses in 2022 which improved in 2023 partially offset by higher selling, general and administrative expenses as a percentage of sales due to continued investments including sales growth incentives and a more normalized cadence of travel and meetings.

The increase in Orthopaedics operating income as a percentage of net sales for 2024 from 2023 was primarily driven by higher sales volumes and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The decrease in Orthopaedics operating income as a percentage of net sales for 2023 from 2022 was primarily driven by higher higher manufacturing and supply chain costs primarily due to increased inventory reserves partially offset by higher unit volumes.

Other Income (Expense), Net

Other income (expense), net was ($197), ($215) and ($158) in 2024, 2023 and 2022. The decrease in net expense in 2024 from 2023 was primarily due to higher interest income partially offset by lower interest expense in 2024. The increase in net expense in 2023 from 2022 was primarily due to the release of accrued interest of $50 in 2022 related to the effective settlement of the United States federal income tax audit for years 2014 through 2018. Refer to Note 11 to our Consolidated Financial Statements for further information and higher interest income in 2023.

Income Taxes

Our effective tax rate was 14.3%, 13.8% and 12.1% for 2024, 2023 and 2022. The effective income tax rate for 2024 decreased from 2023 due to the 2024 deferred tax benefit on the outside basis difference related to the anticipated sale of the Spinal Implants business partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. The effective income tax rate for 2023 increased from 2022 due to the 2022 effective settlement of the United States federal income tax audit for years 2014 through 2018 and the 2022 reversal of deferred income tax on undistributed earnings of foreign subsidiaries partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. Additionally, the effective income tax rates for 2024, 2023 and 2022 reflect the continued lower effective income tax rates as a result of our European operations and certain discrete tax items.

The Organisation for Economic Cooperation and Development (OECD), which represents a coalition of member countries, has put forth two proposed base erosion and profit shifting frameworks that revise the existing profit allocation and nexus rules (Pillar One) and ensure a minimal level of taxation (Pillar Two). On December 12, 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws became effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes could increase tax expense in future periods.

Net Earnings

Net earnings for 2024 increased to $2,993 or $7.76 per diluted share from $3,165 or $8.25 per diluted share in 2023 and $2,358 or $6.17 per diluted share in 2022. Refer to the comments above for discussion of the primary drivers of the change.

Non-GAAP Financial Measures

We supplement the reporting of our financial information determined under accounting principles generally accepted in the United States (GAAP) with certain non-GAAP financial measures, including percentage sales growth in constant currency; percentage organic sales growth; adjusted gross profit; adjusted selling, general and administrative expenses; adjusted research, development and engineering expenses; adjusted operating income; adjusted other income (expense), net; adjusted income taxes; adjusted effective income tax rate; adjusted net earnings; and adjusted net earnings per diluted share (Diluted EPS). We believe these non-GAAP financial measures provide meaningful information to assist investors and shareholders in understanding our financial results and assessing our prospects for future performance. Management believes percentage sales growth in constant currency and the other adjusted measures described above are important indicators of our operations because they exclude items that may not be indicative of or are unrelated to our core operating results and provide a baseline for analyzing trends in our underlying businesses. Management uses these non-GAAP financial measures for reviewing the operating results of reportable business segments and analyzing potential future business trends in connection with our budget process and bases certain management incentive compensation on these non-GAAP financial measures. To measure percentage sales growth in constant currency, we remove the impact of changes in foreign currency exchange rates that affect the comparability and trend of sales. Percentage sales growth in constant currency is calculated by translating current and prior year results at the same foreign currency exchange rate. To measure percentage organic sales growth, we remove the impact of changes in foreign currency exchange rates, acquisitions and divestitures, which affect the comparability and trend of sales. Percentage organic sales growth is calculated by translating current year and prior year results at the same foreign currency exchange rates excluding the impact of acquisitions and divestitures. To measure earnings performance on a consistent and comparable basis, we exclude certain items that affect the comparability of operating results and the trend of earnings. The income tax effect of each adjustment was determined based on the tax effect of the jurisdiction in which the related pre-tax adjustment was recorded. These adjustments are irregular in timing and may not be indicative of our past and future performance. The following are examples of the types of adjustments that may be included in a period:

1. *Acquisition and integration-related costs.* Costs related to integrating recently acquired businesses (e.g., costs associated with the termination of sales relationships, employee retention and workforce reductions, manufacturing integration costs and other integration-related activities), changes in the fair value of contingent consideration, amortization of inventory stepped-up to fair value, specific costs (e.g., deal costs and costs associated with legal entity rationalization) related to the consummation of the acquisition process and legal entity rationalization and acquisition-related tax items.
2. *Amortization of purchased intangible assets.* Periodic amortization expense related to purchased intangible assets.
3. *Structural optimization and other special charges.* Costs associated with employee retention and workforce reductions, the closure or transfer of manufacturing and other facilities (e.g., site closure costs, contract termination costs and redundant employee costs during the work transfers), product line exits (primarily inventory, long-lived asset and specifically-identified intangible asset write-offs), certain long-lived and intangible asset write-offs and impairments and other charges.
4. *Medical device regulations.* Costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the new medical device reporting regulations and other requirements of the European Union.
5. *Recall-related matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve the Rejuvenate, LFIT V40, Wright legacy hip products and other product recalls.
6. *Regulatory and legal matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters.

and the amount of favorable awards from settlements.

7. *Tax matters*. Impact of accounting for certain significant and discrete tax items.

Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names. These adjusted financial measures should not be considered in isolation or as a substitute for reported sales growth, gross profit, selling, general and administrative expenses, research, development and engineering expenses, operating income, other income (expense), net, income taxes, effective income tax rate, net earnings and net earnings per diluted share, the most directly comparable GAAP financial measures. These non-GAAP financial measures are an additional way of viewing aspects of our operations when viewed with our GAAP results and the reconciliations to corresponding GAAP financial measures at the end of the discussion of Consolidated Results of Operations below. We strongly encourage investors and shareholders to review our financial statements and publicly-filed reports in their entirety and not to rely on any single financial measure.

The weighted-average diluted shares outstanding used in the calculation of adjusted net earnings per diluted share are the same as those used in the calculation of reported net earnings per diluted share for the respective period.

Reconciliation of the Most Directly Comparable GAAP Financial Measure to Non-GAAP Financial Measure

2024	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 14,440	$ 7,685	$ 1,466	$ 3,689	$ (197)	$ 499	$ 2,993	14.3 %	$ 7.76
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	46	—	—	46	—	12	34	0.2	0.09
Other acquisition and integration-related (a)	—	(107)	(1)	108	—	23	85	0.2	0.22
Amortization of purchased intangible assets	—	—	—	623	—	128	495	1.0	1.28
Structural optimization and other special charges (b)	59	(77)	(2)	138	1	29	110	0.3	0.29
Goodwill and other impairments (c)	—	—	—	977	—	125	852	(0.6)	2.21
Medical device regulations (d)	9	—	(49)	58	—	14	44	0.1	0.11
Recall-related matters (e)	11	(29)	—	40	—	10	30	0.1	0.08
Regulatory and legal matters (f)	—	(36)	—	36	—	7	29	0.1	0.08
Tax matters (g)	—	—	—	—	—	(28)	28	(0.9)	0.07
Adjusted	$ 14,565	$ 7,436	$ 1,414	$ 5,715	$ (196)	$ 819	$ 4,700	14.8 %	$ 12.19

2023	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 13,058	$ 7,111	$ 1,388	$ 3,888	$ (215)	$ 508	$ 3,165	13.8 %	$ 8.25
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	—	—	—	—	—	—	—	—	—
Other acquisition and integration-related (a)	—	(20)	—	20	—	(25)	45	(0.8)	0.12
Amortization of purchased intangible assets	—	—	—	635	—	132	503	1.2	1.31
Structural optimization and other special charges (b)	39	(130)	(1)	170	—	38	132	0.4	0.34
Goodwill and other impairments (c)	—	—	—	36	—	9	27	0.1	0.08
Medical device regulations (d)	2	—	(94)	96	—	22	74	0.2	0.19
Recall-related matters (e)	—	(18)	—	18	—	4	14	—	0.04
Regulatory and legal matters (f)	—	(92)	—	92	—	29	63	0.4	0.16
Tax matters (g)	—	—	—	—	(8)	(51)	43	(1.2)	0.11
Adjusted	$ 13,099	$ 6,851	$ 1,293	$ 4,955	$ (223)	$ 666	$ 4,066	14.1 %	$ 10.60

2022	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 11,578	$ 6,386	$ 1,454	$ 2,841	$ (158)	$ 325	$ 2,358	12.1 %	$ 6.17
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	12	—	—	12	—	3	9	—	0.02
Other acquisition and integration-related (a)	—	(138)	—	138	—	34	104	0.6	0.27
Amortization of purchased intangible assets	—	—	—	627	—	132	495	1.7	1.30
Structural optimization and other special charges (b)	56	(152)	(87)	295	—	61	234	0.8	0.61
Goodwill and other impairments (c)	—	—	—	270	—	5	265	(1.2)	0.70
Medical device regulations (d)	3	—	(137)	140	—	25	115	0.2	0.30
Recall-related matters (e)	—	15	—	(15)	—	(3)	(12)	—	(0.03)
Regulatory and legal matters (f)	—	(76)	—	76	—	7	69	(0.2)	0.18
Tax matters (g)	—	—	—	—	(75)	(9)	(66)	0.1	(0.18)
Adjusted	$ 11,649	$ 6,035	$ 1,230	$ 4,384	$ (233)	$ 580	$ 3,571	14.1 %	$ 9.34

(a) Charges represent certain acquisition and integration-related costs associated with acquisitions, including:

	2024	2023	2022
Termination of sales relationships	$ 4	$ 5	$ 21
Employee retention and workforce reductions	22	6	33
Changes in the fair value of contingent consideration	8	(1)	(135)
Manufacturing integration costs	3	2	32
Stock compensation payments upon a change in control	22	—	132
Other integration-related activities	49	8	55
Adjustments to Operating Income	**$ 108**	**$ 20**	**$ 138**
Charges for acquisition-related tax provisions	—	—	—
Other income taxes related to acquisition and integration-related costs	23	(25)	34
Adjustments to Income Taxes	**$ 23**	**$ (25)**	**$ 34**
Adjustments to Net Earnings	**$ 85**	**$ 45**	**$ 104**

(b) Structural optimization and other special charges represent the costs associated with:

	2024	2023	2022
Employee retention and workforce reductions	$ 23	$ 69	$ 74
Closure/transfer of manufacturing and other facilities	31	50	83
Product line exits	37	22	34
Termination of sales relationships	8	—	—
Other charges	39	29	104
Adjustments to Operating Income	**$ 138**	**$ 170**	**$ 295**
Adjustments to Other Income (Expense), Net	**$ 1**	**$ —**	**$ —**
Adjustments to Income Taxes	**$ 29**	**$ 38**	**$ 61**
Adjustments to Net Earnings	**$ 110**	**$ 132**	**$ 234**

(c) Goodwill and other impairments represent the costs associated with:

	2024	2023	2022
Goodwill impairments	$ 456	$ —	$ 216
Certain long-lived and intangible asset write-offs and impairments	466	26	8
Product line exits (e.g., long-lived asset and specifically-identified intangible asset write-offs)	55	10	46
Adjustments to Operating Income	**$ 977**	**$ 36**	**$ 270**
Adjustments to Income Taxes	**$ 125**	**$ 9**	**$ 5**
Adjustments to Net Earnings	**$ 852**	**$ 27**	**$ 265**

(d) Charges represent the costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the medical device reporting regulations and other requirements of the new medical device regulations in the European Union.

(e) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain recall-related matters.

(f) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters and the amount of favorable awards from settlements.

(g) Benefits / (charges) represent the accounting impact of certain significant and discrete tax items, including:

	2024	2023	2022
Adjustments related to the transfer of certain intellectual properties between tax jurisdictions	$ (185)	$ (89)	$ (182)
Certain tax audit settlements	(1)	24	162
Reversal of deferred income tax on undistributed earnings of foreign subsidiaries	—	—	71
Deferred tax benefit on outside basis related to the anticipated sale of the Spinal Implants business	170	—	—
Other significant and discrete tax items	(12)	14	(60)
Adjustments to Income Taxes	**$ (28)**	**$ (51)**	**$ (9)**
Benefits for certain tax audit settlements	—	(9)	(45)
Other tax related adjustments	—	1	(30)
Adjustments to Other Income (Expense), Net	**$ —**	**$ (8)**	**$ (75)**
Adjustments to Net Earnings	**$ 28**	**$ 43**	**$ (66)**

FINANCIAL CONDITION AND LIQUIDITY

Net cash provided by (used in):	2024	2023	2022
Operating activities	$ 4,242	$ 3,711	$ 2,624
Investing activities	(3,000)	(962)	(2,924)
Financing activities	(525)	(1,594)	(749)
Effect of exchange rate changes	(36)	(28)	(51)
Change in cash and cash equivalents	**$ 681**	**$ 1,127**	**$ (1,100)**

We believe our financial condition continues to be of high quality, as evidenced by our ability to generate substantial cash from operations and to readily access capital markets at competitive rates despite the current macroeconomic environment. Operating cash flow provides the primary source of cash to fund operating needs and capital expenditures. Excess operating cash is used first to fund acquisitions to complement our portfolio of businesses. Other discretionary uses include dividends and share repurchases. We supplement operating cash flow with debt to fund our activities as necessary. Our overall cash position reflects our business results and a global cash management strategy that takes into account liquidity management, economic factors and tax considerations.

Operating Activities

Cash provided by operating activities was $4,242, $3,711 and $2,624 in 2024, 2023 and 2022. The increase in 2024 was primarily due to higher cash earnings partially offset by changes in working capital. The increase in 2023 from 2022 was primarily due to higher net earnings and increased collections on accounts receivable.

Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy

Warehouser

9960 Mayland Drive, Suite 300
Henrico, VA 23233

www.dhp.virginia.gov/pharmacy
Email: pharmbd@dhp.virginia.gov

Main: 804.367.4456
Fax: 804.527.4472

Facility License or Permit Number:	0216000200	**Inspection Type:**	Routine
Facility Name:	K2M, Inc.	**Inspection Results:**	No Deficiencies
Special or Limited Use?	No	**Inspection Date:**	10/15/2024
Controlled Substances Registration Number (CSR): (If applicable)		**Inspector Name:**	Victoria McGhee
CSR Inspection conducted concurrent with this inspection:		**Responsible Party:**	Megan Carnes
Address:	600 Hope Parkway SE	**Responsible Party License Number:**	megan.carmes@stryker.com
City:	Leesburg	**Responsible Party Email Address):**	statelicensing1@stryker.com
State:	VA	**Individual on Duty:**	Megan Carnes
Zip Code:	20175	**Inspection Emailed To (person):**	Megan Carnes
Telephone number:	571-919-2000	**Inspection Emailed To (email address):**	statelicensing1@stryker.com
Fax number:	N/A		
Email address:	statelicensing1@stryker.com		
Drug Schedules (Select all that apply):			
Type of Products (Select all that apply):	Prescription Devices		

Hours of Operation		**Is facility open 24/7?**	No
	Start Time (hh:mm)	**End Time (hh:mm)**	**Closed**
Sunday			Closed
Monday	8:00	0:00	
Tuesday	8:00	0:00	
Wednesday	8:00	0:00	
Thursday	8:00	0:00	
Friday	8:00	0:00	
Saturday			Closed

State & Federal Licensure Information		
License/Registration Agency	**License/Registration Number**	**Name on License/Registration**

Inspector Comments

The site manufactures and packages spine implants. The product is sent to the health care professional or sales rep for distribution to the health care professional.

Virginia Board of Pharmacy

Wholesale Distributor, Warehouser, Third Party Logistics Provider, Restricted Manufacturer, Non-restricted Manufacturer

Inspection Report

	General	Result	Notes
54.1-3430	Permits issued under the provisions of this chapter shall be displayed in a conspicuous place in the factory or other place of business for which issued.	Compliant	
18VAC110-50-30	A license, permit, or registration shall not be issued to any wholesale distributor, manufacturer, warehouser, or third-party logistics provider to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license, permit, or registration is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.	Compliant	
	If a wholesale distributor, manufacturer, warehouser, or third-party logistics provider engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of any Schedules II through V controlled substances, it shall also obtain a controlled substances registration from the board in accordance with § 54.1-3422 of the Code of Virginia, and shall also be duly registered with DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of controlled substances.	Not Applicable	The site only stocks prescription devices.
	A licensee or permit holder proposing to change the location of an existing license or permit, or make structural or security system changes to an existing location, shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.	Not Applicable	
	The proposed location, structural changes, or security system changes shall be inspected by an authorized agent of the board prior to issuance of a license or permit.	Not Applicable	
	Prescription drugs shall not be stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff.	Not Applicable	There are no prescription drugs.
	Security of Drugs	**Result**	**Notes**
18VAC110-50-40	The holder of the license or permit shall restrict access to all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution, or quality control of the controlled substance inventory and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.	Compliant	
18VAC110-50-40	The holder of the license, permit, or registration, **except for those distributors of only medical gases other than nitrous oxide**, shall install a device for the detection of breaking subject to the following conditions:	Not Applicable	No prescription drugs are stocked. There is no alarm system. There is key/badge access to authorized areas.
	1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.		
	2. One communication line installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards to include wireless motion sensors.		
	3. The device shall be maintained in operating order, shall have an auxiliary source of power, and shall be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.		
	4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.		
	5. Access to the alarm system shall be restricted to the person named on the application as the responsible party or to persons specifically designated in writing in a policy and procedure manual.		
	6. The system shall be activated whenever the drug storage areas are closed for business.		
	Security Alarm System — **Was alarm tested?**	No	**Notes**

Mode of Communication		**Security Company**	
Primary:		**Test Verified By:**	
Secondary:		**Test Verified By:**	
Describe if Other:			

Number of Sensors	**90**	**180**	**360**	**Contact**	**Other**	**Camera**

Virginia Board of Pharmacy
Wholesale Distributor, Warehouser, Third Party Logistics Provider, Restricted Manufacturer, Non-restricted Manufacturer
Inspection Report

	Safeguards Against Diversion of Drugs	**Result**	**Notes**
18VAC110-50-40	Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.	Not Applicable	
	1. The holder of the license, permit, or registration shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.		
	2. The holder of the license, permit, or registration shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.		
	Prescription drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, warehouser, third-party logistics provider, nonresident wholesale distributor, nonresident warehouser, nonresident third-party logistics provider, or nonresident manufacturer and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient.		
	Storage	**Result**	**Notes**
18VAC110-50-50	All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements of USP-NF.	Compliant	
	If no specific storage requirements are established for a drug or a device, it may be held at controlled room temperature, as defined in USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.	Compliant	Devices are held at room temperature.
	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, or logs shall be utilized to document proper storage of prescription drugs.	Not Applicable	
	Packaging of the prescription drugs should be in accordance with USP-NF standards.	Not Applicable	
	Schedule II – V controlled substances shall be separated from Schedule VI prescription drugs and stored in a secure area in accordance with DEA security requirements and standards.	Not Applicable	
	Any facility shall be of adequate size and construction and have the proper equipment necessary for the proper storage of prescription drugs and devices as set forth in this section.	Compliant	
	Disposal of Drugs by Authorized Collectors	**Result**	**Notes**
18VAC110-50-51	Any **manufacturer, wholesale distributor, or reverse distributor** wishing to accept for return a previously dispensed drug in Schedules II through V for the purpose of destruction from an ultimate user, or a person lawfully entitled to dispose of an ultimate user decedent's property, shall first be authorized by the DEA as a collector. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with federal and state law. 1. Prior to collecting drugs, an authorized collector shall submit in writing to the board: a. The name, address, and license number, if applicable, of the facility. b. The intended method or methods of collection (i.e., collection receptacle or mail-back program); and c. Signature of the responsible party. 2. If an authorized collector chooses to cease acting as a collector, the responsible party shall notify the board within 30 days.	Not Applicable	
	Records of Drugs in Schedules I, II, III, IV & V	**Result**	**Notes**
§54.1-3404	Except as set forth in subsection G, every person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business. If there are no controlled substances on hand at that time, he shall record this fact as part of the inventory. An inventory taken by use of an oral recording device shall be promptly reduced to writing and maintained in a written, typewritten or printed form. Such inventory shall be made either as of the opening of business or as of the close of business on the inventory date.	Not Applicable	

Virginia Board of Pharmacy

Wholesale Distributor, Warehouser, Third Party Logistics Provider, Restricted Manufacturer, Non-restricted Manufacturer

Inspection Report

§54.1-3404	After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.	Not Applicable	
	The record of such drugs received shall in every case show the date of receipt, the name and address of the person from whom received and the kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture, and the date of such production or removal from process of manufacture. The record shall in every case show the proportion of morphine, cocaine, or ecgonine contained in or producible from crude opium or coca leaves received or produced.	Not Applicable	
	The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were sold, administered or dispensed, and the kind and quantity of drugs. Any person selling, administering, dispensing or otherwise disposing of such drugs shall make and sign such record at the time of each transaction. The keeping of a record required by or under the federal laws, containing substantially the same information as is specified above, shall constitute compliance with this section, except that every such record shall contain a detailed list of any drugs lost, destroyed or stolen, the kind and quantity of such drugs, and the date of the discovery of such loss, destruction or theft. The form of records shall be prescribed by the Board.	Not Applicable	
	Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs.	Not Applicable	
	Within 30 days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.	Not Applicable	
	All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded.	Not Applicable	

Virginia Board of Pharmacy

Wholesale Distributor, Warehouser, Third Party Logistics Provider, Restricted Manufacturer, Non-restricted Manufacturer

Inspection Report

	Delivery of Medical Devices on Behalf of a Medical Equipment Supplier	Result	Notes
Complete if the Medical Equipment Supplier utilizes a permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider or registered nonresident manufacturer or nonresident wholesale distributor for delivery.			
§54.1-3415.1	A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user or consumer **on behalf of a medical equipment supplier**, provided that:		The site only delivers their products directly to the health care provider. No products are delivered on behalf of a MES.
	1. Such delivery occurs at the direction of a medical equipment supplier that has received a valid order from a prescriber authorizing the dispensing of such prescription device to the ultimate user or consumer.	Not Applicable	
	2. The manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider has entered into an agreement with the medical equipment supplier for such delivery.	Not Applicable	
18VCA110-50-55 (A)	**In accordance with provisions of subsection A of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third party logistics provider, nonresident third party logistics provider, warehouser, or nonresident warehouser licensed, permitted or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier.** **1. Such delivery shall only occur in accordance with an agreement between a delivering entity named in subsection A of this section and a medical equipment supplier in compliance with law and regulation.** **2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and an individual medical equipment supplier or multiple medical equipment suppliers under shared ownership. The agreement shall be applicable to all ultimate users or consumers receiving services from the medical equipment supplier who require delivery of Schedule VI prescription devices.** **3. The medical equipment supplier shall represent to the delivering entity that it has complied with provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a valid order from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of orders of prescribers shall be the responsibility of the medical equipment supplier, upon request of the board or delivering entity.**		
§54.1-3415.1	A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence **to be administered by persons authorized to administer such devices**, provided that:		
	1. Such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence.	Not Applicable	
	2. The medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.	Not Applicable	
18VAC110-50-55 (B)	**B. In accordance with provisions of subsection B of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third party logistics provider, nonresident third party logistics provider, warehouser, or nonresident warehouser permitted, licensed, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate users or consumers residence to be administered by persons authorized to administer such devices, provided that:** **(i) such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence and** **(ii) the medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.** **1. Such delivery shall only occur in accordance with an agreement between a delivering entity authorized in subsection B of this section and a medical director of a home health agency, nursing home, assisted living facility, or hospice, and in compliance with law and regulation.** **2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and the medical director of an individual home health agency, nursing home, assisted living facility, or hospice, or multiple such entities under shared ownership. The agreement shall be applicable to all ultimate users or consumers of the home health agency, nursing home, assisted living facility, or hospice who require delivery of Schedule VI prescription devices.** **3. The home health agency, nursing home, assisted living facility or hospice shall represent to the delivering entity that it has complied with provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a request from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of the request from a prescriber shall be the responsibility of the home health agency, nursing home, assisted living facility or hospice, upon request of the board or delivering entity.**		
18VAC110-50-55 (C)	**The agreement, as required by A. 1 and B. 1, shall be in written or electronic format and shall be retained in a format available upon request to the board at all times the agreement is in effect, and for two years after the date the agreement is terminated or concluded.**		
18VAC110-50-55 (D)	**An agreement shall not contain any patient specific or patient health information that would be subject to the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)**		

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: LifeScience Logistics, LLC

Physical Address: 5200 Tradeport Drive

City: Memphis State: TN Zip: 38141

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.lslog.com

Name of Designated Representative (DR): Harold Preston Fagan II

Licensing Company Email: LSL@slsny.com DR Email: HFagan@lslog.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: Drugs (Human OTC, Biologics), Devices (OTC, Containing a Drug, Rx Convenience Kit Containing a drug component)	☐ Warehouse
☒ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Distribution sites within organization, Manufacturers		☒ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
07/21/2016	03/16/2017	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2016-3687	CO Department of Regulatory Agencies

Reason/Charge
Discipline was a result of CO not being notified of a change of DR within 30 days

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
LifeScience Logistics, LLC

Provide explanation below:

Please see attached documents

Discipline already disclosed
WHo 3946
WHo 3949

David Christopher Cheetham

Original Signature (electronic, copies or stamps not accepted)

30 Sept 2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/26/2016	04/30/2018	CA	Sacramento	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2017 78097	CA State Board of Pharmacy

Reason/Charge
Operated without a DR

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
LifeScience Logistics, LLC

Provide explanation below:

Please see attached documents

David Christopher Cheetham

Original Signature (electronic, copies or stamps not accepted)

30 Sept 2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/16/2018	10/26/2018	AL	Birmingham	Jefferson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
18-L-0075	Alabama State Board of Pharmacy

Reason/Charge
Domino discipline based on the citation and fine from CA BOP for failure to designate a new DR

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
LifeScience Logistics, LLC

Provide explanation below:

Please see attached documents

David Christopher Cheetham

Original Signature (electronic, copies or stamps not accepted)

30 Sept 2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/23/2021	05/23/2023	CA	Sacramento	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2021 95502	CA Board of Pharmacy

Reason/Charge
Citation for failing to notify change of DR within 30 days & operating without a DR

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
LifeScience Logistics, LLC

Provide explanation below:

Please see attached documents

David Christopher Cheetham

Original Signature (electronic, copies or stamps not accepted)

30 Sept 2025

Date

AL - Discipline Doc
Case No: 18-L-0075

ALABAMA
BOARD OF PHARMACY

Donna Yeatman, R.Ph.
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
(205) 981-2330 Fax
www.albop.com

MEMBERS 2018

David Darby, R.Ph.
President

Ralph Sorrell, R.Ph.
Treasurer

Brenda Denson, PharmD

Chris Phung, R.Ph.

October 29, 2018

Lifescience Logistics, LLC
Permit #'s 193417 and 195184
1105 East Northfield Drive
Brownsburg, IN 46112

RE: Final order

Dear Lifescience Logistics LLC,

Enclosed you will find a FINAL ORDER resulting from your hearing before the Board. While the entire order is important, I particularly direct your attention to the portion of the Order setting forth the mandatory obligation of your payment of a fine and costs. As you will see, those amounts are due within a specified period of time from the date of the Final Order and not the date of this letter. The order also states that your renewal will not be processed until the fine has been paid. Permit # 195184 renewal has already been issued so it has been placed on administrative hold until fine is paid.

If the referenced fine and costs are not received by the Board within the prescribed period of time, or special arrangements have not been made with the Secretary of the Board, additional charges will be brought against you.

Sincerely,

Wendy Passmore

Wendy Passmore
Operations Manager
Alabama State Board of Pharmacy
Phone 205-981-4764
Fax 205-803-6481
Email - wpassmore@albop.com

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
LIFESCIENCE LOGISTICS, LLC	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit Number 193417	)	Case Number 18-L-0075
	)	
and	)	
	)	
Third Party Logistics Permit Number 195184	)	

FINAL ORDER

On October 16, 2018 this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board") on a Complaint against Lifescience Logistics, LLC (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Findings of Facts

1. The Respondent is a Wholesale Distributor which the Board issued permit number 193417 and also a Third Party Logistics facility which the Board issued permit number 195184.

2. The Respondent was notified of the charges by certified mail at the address provided to the Board by the Respondent, however, the notice was returned by the United States Postal Service with the indication "return to sender insufficient address unable to forward". (Board's Exhibits One and Two)

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent's facility is located at 1105 East Northfield Drive, Brownsburg,

Indiana 46112.

5 On April 30, 2018 the Board of Pharmacy, Department of Consumer Affairs, State of California, issued a Citation and Fine to the Respondent for failure to designate a new representative in charge for a period of four hundred and twenty-eight (428) days. (Board's Exhibit One "A").

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction of this cause pursuant to Code of Alabama (1975), § 34-23-32, Code of Alabama (1975), § 34-23-32.1 , Code of Alabama (1975), § 34-23-92 (11) and (12), Code of Alabama (1975), § 41-22-12 and Board Rule 680-X-2.23.

2. The Respondent was properly notified of the charges, failed to appear, was not represented by counsel and did not contest the matter in any manner.

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent's wholesale distributor permit and third party logistics permit in the state of Alabama are due to have disciplinary sanctions imposed in that it is guilty of violating Board Rule 680-X-2.23 (3) (k) (1) and Board Rule 680-X-2.23 (3) (k) (3) and it was not qualified to possess the permits, and/or its operation was not consistent with the public safety or endangers the public health of the citizens of this state based upon violating California law relating to non-resident wholesales as set out in the Citation and Fine entered by the California State Board of Pharmacy on April 30, 2018 and/or the failure to have a licensed designated representative in charge for Four Hundred Twenty-Eight (428) days as described in the referenced Citation and Fine.

DocuSign Envelope ID: 98CF4B8B-4525-4DCD-BFAE-6E1F661FD2B5

ORDER

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

1. The Respondent shall pay the Board an administrative fine of One Thousand ($1,000.00) Dollars within thirty (30) days of the date of this Final Order and future applications for renewal shall not be granted unless said fine has been paid; and

2. Any future violations of this Order, the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rule of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state may, upon hearing and proof thereof, result in further disciplinary sanctions.

DONE and ORDERED, this 26 day of October 2018.

Mr. David S. Darby, R.Ph.., President
Alabama State Board of Pharmacy

Copies to:
Lifescience Logistics, LLC
Ms. Donna C. Yeatman, R. Ph., Executive Secretary
Mr. James S. Ward, Esq.
Mr. Vance L. Alexander, Esq.

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 30, 2018

DATED MATERIAL ENCLOSED

LIFESCIENCE LOGISTICS LLC
ATTN: MAX KAMHI, MEM
4475 SOUTH FULTON PKWY BLDG 5 STE C
ATLANTA, GA 30349

RE: CI 2017 78097
LIFESCIENCE LOGISTICS LLC
OSD 6246

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- May 30, 2018: Unless the Citation is contested payment of fine(s) must be received by the Board.
- May 14, 2018: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- May 30, 2018: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Ericka Busby, Enforcement Analyst at (916) 574-7731.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **May 30, 2018.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Ericka Busby
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7731

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than May 14, 2018 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than May 30, 2018 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have questions regarding any documents enclosed with the Citation, please contact Jennifer Sevilla, Associate Enforcement Analyst, at (916) 574-7924.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2017 78097	LIFESCIENCE LOGISTICS LLC, OSD 6246

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	Citation without a fine
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	$900.00

CONDUCT:

Business and Professions Code section 4161(j) requires every non-resident wholesaler to be managed by a licensed designated representative-in-charge (DRIC) who shall be responsible for compliance, and to notify the Board in writing, on a form designed by the Board, within 30 days of the date when a DRIC ceases to act as the DRIC. Specifically, on Oct. 26, 2016, Lifescience Logistics LLC notified the Board 55 days after the date John D Anderson (EXC 20346) ceased to act as DRIC on Sep. 2, 2016.

Business and Professions Code section 4161(j) requires every non-resident wholesaler to be managed by a licensed designated representative-in-charge (DRIC). Specifically, Lifescience Logistics LLC operated for 428 days without a DRIC, between the date John D Anderson (EXC 20346) ceased to act as DRIC on Sep. 2, 2016, and the date Perry Utley (EXC 23899) was licensed as a designated representative on Nov. 3, 2017.

CITATION ISSUED ON: April 30, 2018	TOTAL AMOUNT OF FINE(S): $900.00

PAYMENT OF FINE(S) DUE BY: May 30, 2018

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2017 78097	LIFESCIENCE LOGISTICS LLC, OSD 6246

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4161 subd. (j)	A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge	Citation without a fine
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CONDUCT:

Business and Professions Code section 4161(j) requires every non-resident wholesaler to be managed by a licensed designated representative-in-charge (DRIC) who shall be responsible for compliance, and to notify the Board in writing, on a form designed by the Board, within 30 days of the date when a DRIC ceases to act as the DRIC. Specifically, on Oct. 26, 2016, Lifescience Logistics LLC notified the Board 55 days after the date John D Anderson (EXC 20346) ceased to act as DRIC on Sep. 2, 2016.

Business and Professions Code section 4161(j) requires every non-resident wholesaler to be managed by a licensed designated representative-in-charge (DRIC). Specifically, Lifescience Logistics LLC operated for 428 days without a DRIC, between the date John D Anderson (EXC 20346) ceased to act as DRIC on Sep. 2, 2016, and the date Perry Utley (EXC 23899) was licensed as a designated representative on Nov. 3, 2017.

CITATION ISSUED ON: April 30, 2018	TOTAL AMOUNT OF FINE(S): $900.00

PAYMENT OF FINE(S) DUE BY: May 30, 2018

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: LIFESCIENCE LOGISTICS LLC

License No: OSD 6246

Citation Number : CI 2017 78097

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check ☐ I contest the Citation and request an Office Conference.

Check One:

☐ I contest the entire Citation or

☐ specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

If more space is needed attach additional sheets of paper.

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Telephone: (Business) (___) _____ Residence: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: State Board of Pharmacy
Attn: Jennifer Sevilla
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834-1924
(916) 574-7925

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check ☐ I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:	Citation Case No : CI 2017 78097
LIFESCIENCE LOGISTICS LLC OSD 6246 Respondent	NOTICE OF APPEAL (Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATED _____ _____
(Respondent)

Mailing Address of Respondent:

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

_____
(Attorney's Name

_____
(Street Address)

_____ (___)_____
(City (State) (Zip) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: LIFESCIENCE LOGISTICS LLC, OSD 6246
Citation and Fine CI 2017 78097

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On April 30, 2018, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
LIFESCIENCE LOGISTICS LLC ATTN: MAX KAMHI, MEM 4475 SOUTH FULTON PKWY BLDG 5 STE C ATLANTA, GA 30349	7016 1970 0001 0142 6645

I declare under penalty of perjury that the forgoing is true and correct.

Executed on April 30, 2018, at Sacramento, California.

DECLARANT
Ericka Busby
Enforcement Analyst

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 30, 2018

LIFESCIENCE LOGISTICS LLC
ATTN: PERRY UTLEY, EIC
4475 SOUTH FULTON PKWY BLDG 5 STE C
ATLANTA, GA 30349

LIFESCIENCE LOGISTICS LLC
ATTN: MAX KAMHI, MEM
4475 SOUTH FULTON PKWY BLDG 5 STE C
ATLANTA, GA 30349

RE: CI 2017 78097
LIFESCIENCE LOGISTICS LLC
OSD 6246

This is in response to the administrative fine provided to the board for the above referenced citation. The payment has been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Enforcement Analyst, Ericka Busby at (916) 574-7731.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 23, 2023

LIFESCIENCE LOGISTICS, LLC
ATTN: ALEXANDER BOVA, EIC
3860 S 500 E STE 200
WHITESTOWN, IN 46075

RE: CI 2021 95502
LIFESCIENCE LOGISTICS, LLC
OSD 8005

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Citation and Fine Analyst, Suelynn Yee at (916) 518-3013.

Sincerely,

Suelynn Yee
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 23, 2023

LIFESCIENCE LOGISTICS, LLC
ATTN: RICHARD BEENY, CEO
3860 S 500 E STE 200
WHTESTOWN, IN 46075

RE: CI 2021 95502
LIFESCIENCE LOGISTICS, LLC
OSD 8005

This is in response to the administrative fine and proof of abatement provided to the board for the above referenced citation. The payment and documentation have been received and accepted as satisfactorily resolving the matter.

Please be advised that this citation has become a part of the board's records and constitutes a public record for purposes of disclosure.

If you have any questions regarding this matter, please contact the Citation and Fine Analyst, Suelynn Yee at (916) 518-3013.

Sincerely,

Suelynn Yee
Citation and Fine Analyst

LifeScience Logistics

5100 Olympus Blvd, Suite 100 Dallas, TX 75019

27 February 2025

RE: LSL Explanation for Colorado Citation from 2017

To Whom It May Concern:

This memo provides an explanation of the Colorado State Board of Pharmacy's citation and fine of Life Science Logistics in March 2017.

On April 27th, 2016, the Board received an Application for Change of Designated Representative (DR) from LifeScience Logistics, LLC. The form indicated the prior DR, Thomas Kennedy, disassociated November 16th, 2015, and that Henry Tillman took over as the new DR the same day. However, the resume for the Designated Representative was received July 18th, 2016. Therefore, approximately 180 days had transpired from the time the previous Designated Representative left the position until the time the application was received: and approximately 240 days had transpired from the time the previous Designated Representative left the position, and the new Designated Representative's resume was received.

This finding was determined to be a violation of Board Rule 15.01.14(c) states that any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within 30 calendar days of such change. An administrative fine was issued.

In response, the administrative fine was paid, and proof of abatement provided to the board for the citation. The payment and documentation were received and accepted as satisfactorily resolving the matter.

Please do not hesitate to contact us if there are any additional questions.

Sincerely,

Bozie Madison
Directory of Quality and Compliance
Mobile: 713.494.0127
Email: bmadison@lslog.com
Website: www.lslog.com

COLORADO
Department of
Regulatory Agencies

Healthcare Branch
State Board of Pharmacy

July 21, 2016

Lifescience Logistics
Attn: Henry Tillman
1105 E. Northfiled Dr. Ste 300-400
Brownsburg, IN 46112-2529

RE: **Case 2016-3687 concerning LifeScience Logisitics, WHO 7828**

Dear Mr. Tillman:

The Colorado State Board of Pharmacy ("Board") has received the attached complaint regarding the conduct of the Board-registered out-of-state prescription drug wholesaler detailed above. The Board is investigating this complaint. It is being sent to you as the designated representative of the above listed out-of-state prescription drug wholesaler. The first step in the process is to obtain your response to the allegations raised in the complaint. At this point, no assumption has been made about the truth or validity of any information provided to the Board.

Please send a written response within thirty (30) days of the date of this letter as indicated above. An earlier response may expedite the Board's review of this matter. To facilitate an efficient and timely review, please type your response. If this is not possible, please legibly print your response.

We encourage you to respond electronically. If you do, please submit the response to jean.rowcliffe@ state.co.us. Please scan and attach any relevant documents. Address all correspondence to the Board.

Also, please be sure that any copies submitted with your response are legible. Be sure to include the case number listed above on all correspondences and address your response to my attention.

It is the policy of the Division of Professions and Occupations to copy your attorney (if you are represented) on all correspondences in order to assure that your attorney is aware of the developments in your case. If you are represented by an attorney in this matter, please provide the Board in writing with your attorney's contact information. If the Board already has your attorney's contact information, your attorney name should be identified below as a carbon copy of "cc," indicating that a copy of this

letter was sent to that attorney. If at any time it appears that the Board does not have the correct information regarding your legal representation, please update the Board and provide your attorney with a copy of all correspondences from the Board.

We strongly encourage you to begin preparing your response to the complaint as soon as possible, as extensions to the thirty day response time will not be granted except in very limited circumstances. Additionally, if you choose to be represented by an attorney, please contact him or her immediately. A delay in doing so will not be grounds for an extension.

Following receipt of your response, the Board will review the complaint and your response thereto. The Board will then determine what further action, if any, is warranted. Please note you will be advised in writing of the Board's disposition of this complaint.

Thank you for your cooperation and prompt attention to this matter. If you have any questions, please contact me at jean.rowcliffe@state.co.us or (303) 894-7897.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Jean Rowcliffe
Complaint Analyst

Enclosures: Q&A Brochure
Complaint

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A This is a new facility

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FL

Parent Company (if any): LifeScience Logistics, LP (94%)& LSL HoldCo, LLC (6%)

Corporation/Organization Name: LifeScience Logistics, LLC

Mailing Address: c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Email: LSL@slsny.com

Contact Person Name: Christine Cannon

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

LifeScience Logistics, LLC

Facility Name

David Christopher Cheetham

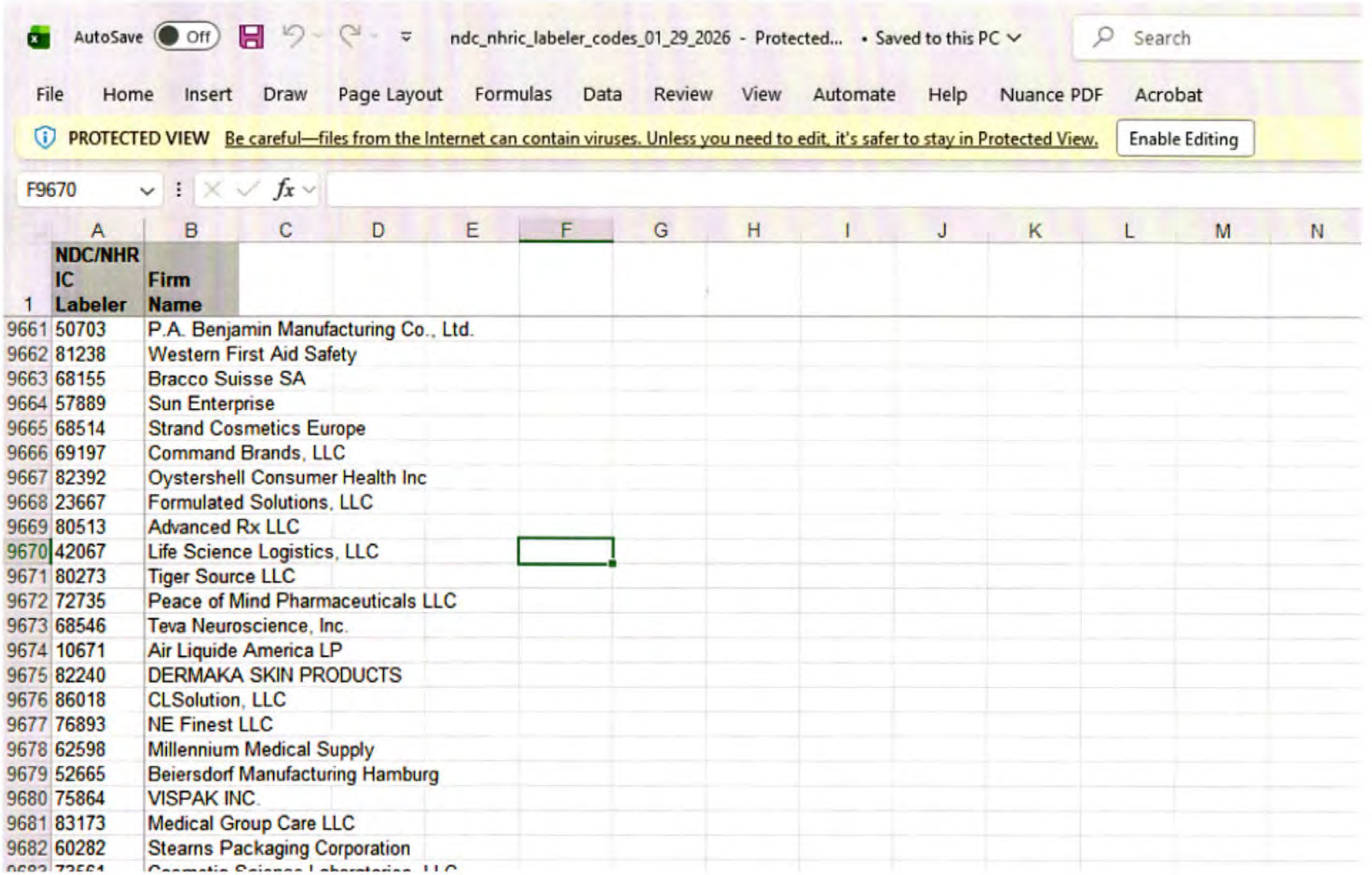
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

30 Sept 2025

Date

Board Use Only	Date Received: 12/8/25	Amount: $10000 CK 9238



	A	B
1	**NDC/NHRIC Labeler**	**Firm Name**
9661	50703	P.A. Benjamin Manufacturing Co., Ltd.
9662	81238	Western First Aid Safety
9663	68155	Bracco Suisse SA
9664	57889	Sun Enterprise
9665	68514	Strand Cosmetics Europe
9666	69197	Command Brands, LLC
9667	82392	Oystershell Consumer Health Inc
9668	23667	Formulated Solutions, LLC
9669	80513	Advanced Rx LLC
9670	42067	Life Science Logistics, LLC
9671	80273	Tiger Source LLC
9672	72735	Peace of Mind Pharmaceuticals LLC
9673	68546	Teva Neuroscience, Inc.
9674	10671	Air Liquide America LP
9675	82240	DERMAKA SKIN PRODUCTS
9676	86018	CLSolution, LLC
9677	76893	NE Finest LLC
9678	62598	Millennium Medical Supply
9679	52665	Beiersdorf Manufacturing Hamburg
9680	75864	VISPAK INC.
9681	83173	Medical Group Care LLC
9682	60282	Stearns Packaging Corporation

List of Officers

LifeScience Logistics®

June 27, 2024

List of Officers

As of today, the current list of corporate officers of Life Science Logistics, LLC are as follows:

Corinna Ulrich – General Counsel and Corporate Secretary
David Christopher Cheetham – Chief Executive Officer

LifeScience Logistics, LLC

Corporate Address: 3100 Olympus Blvd., Suite 100, Dallas, TX 75019 USA
FEIN: 20-4870652
www.lslog.com

Drug Labeler Code: 42067
Incorporation State: FL
Incorporation Date: 05/12/2006

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
TMC	5200 Tradeport Drive Memphis, TN 38141 County: Shelby	N/A	N/A - No CS	119554222	No	(469) 844-3699	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority
Harold Preston Fagan II	19 Troup Ct Acworth, GA 30101	Director of Commercial Operations	

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority
LifeScience Logistics, LP	3100 Olympus Blvd. Suite 100 Dallas, TX 75019		94	
LSL HoldCo, LLC	3100 Olympus Blvd Dallas, TX 75019		6	

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority
David Christopher Cheetham	[redacted]	Chief Executive Officer	
Corinna Ulrich		General Counsel and Corporate Secretary	

Disciplinary History: CO 2017, AL 2018, CA 2023

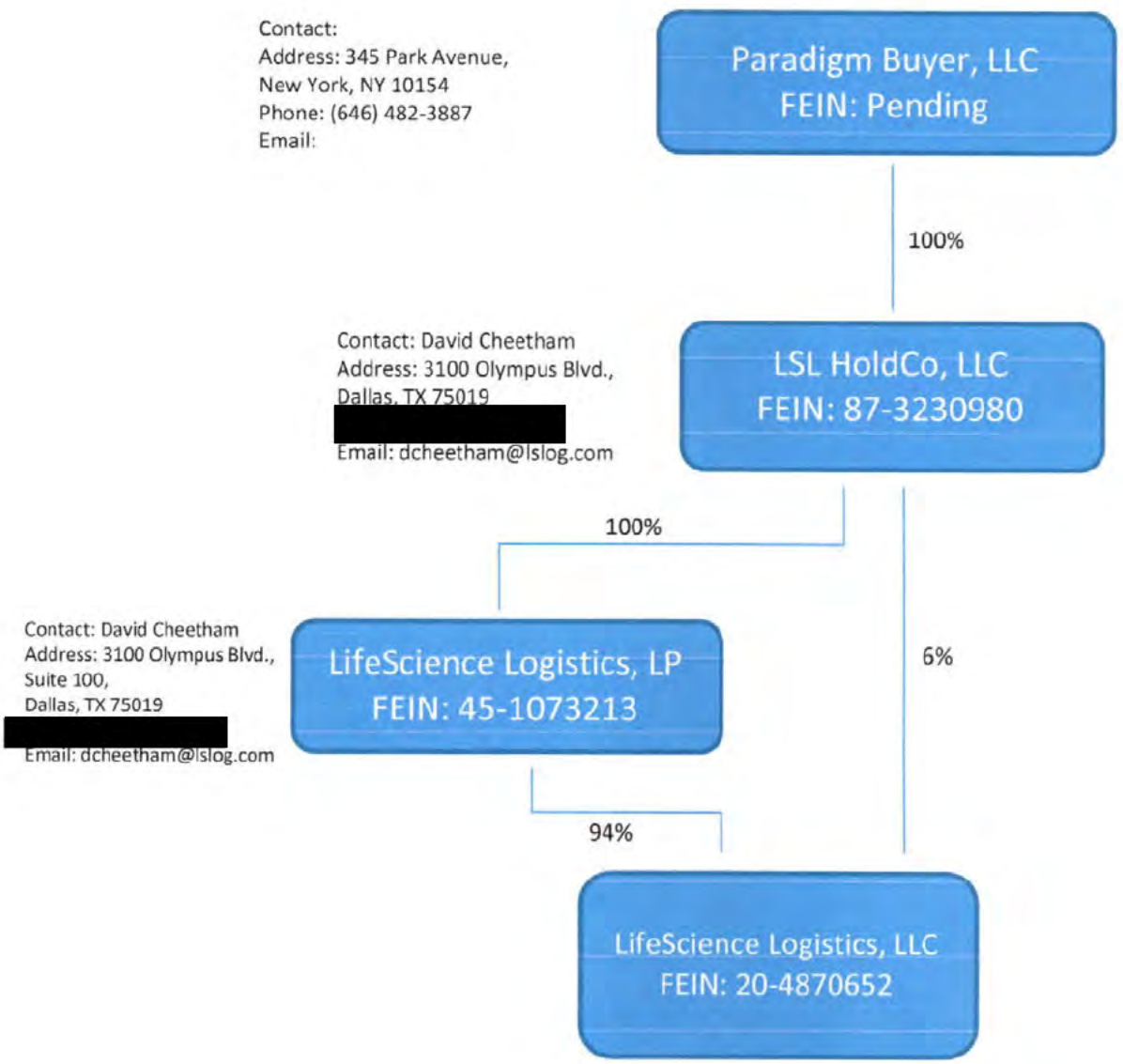
For licensing issues, please contact State License Servicing, LLC (845) 544-2482 LSL@slsny.com

Company Particulars

List of Owners

LifeScience Logistics®

ORGANIZATIONAL CHART



Good Standing

State of Florida
Department of State

I certify from the records of this office that LIFE SCIENCE LOGISTICS, LLC is a limited liability company organized under the laws of the State of Florida, filed on May 12, 2006.

The document number of this limited liability company is L06000049668.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on February 11, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Second day of September, 2025

Secretary of State

Tracking Number: 0154775378CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Home State (TN) Verification of License

Last Updated: 11/20/2025

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy-Manufacturer/Wholesaler/Distributor
County = All
Results = 2

Click here to return to the search page

1	LifeScience Logistics, LLC 5200 Tradeport Drive Memphis, TN 38141 Attn: Harold Preston Fagan II 469-84-3699	Rank: Third Party Logistics Facility License Number: 00011896 Status: Licensed Date of Original Licensure: 11/13/2025 Date of Expiration: 11/30/2027 **No Disciplinary Actions**
2	LifeScience Logistics, LLC 3530 Brightleaf Lane Apex, NC 27523 Attn: Robert Francis Stemberg 469-844-3699	Rank: Third Party Logistics Facility License Number: 00011898 Status: Licensed Date of Original Licensure: 09/16/2025 Date of Expiration: 09/30/2027 **No Disciplinary Actions**

Proof of Labeler Code



FY2021

CERTIFICATE OF REGISTRATION

This certifies that:

Life Science Logistics LLC
1105 E. Northfield Drive
Brownsburg, IN 46112
United States

is registered with the U.S. Food and Drug Administration for the statutory filing period applicable to U.S. FY 2021 pursuant to part 207 of Title 21, U.S. Code of Federal Regulations.

DUNS Number:	**96-872-7565**
Labeler Code:	**42067**
FEI:	**3009057691**
Registrant Contact:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Filing was performed during the October 1 - December 31, 2020 statutory period, and renewal is not required until the next statutory period of October 1 - December 31, 2021. Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate, until the end of the year stated above, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of registration or possession of registration number or NDC number is misleading and constitutes misbranding. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: November 9, 2020

©2007-2021 Registrar Corp

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/1/2026 — 6/30/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: Lockton Companies, LLC 444 W. 47th St., Ste. 900 Kansas City MO 64112-1906 (816) 960-9000 kcasu@lockton.com	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1523533: LIFE SCIENCE LOGISTICS, LLC 3100 OLYMPUS BLVD. SUITE 100 DALLAS TX 75019	INSURER A: Federal Insurance Company — NAIC # 20281 INSURER B: Great Northern Insurance Company — 20303 INSURER C: Chubb Indemnity Insurance Company — 12777 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 19474248 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT X LOC OTHER:	Y	N	99510817	7/1/2025	7/1/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded $
B	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY	N	N	73635009	7/1/2025	7/1/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX $ XXXXXXX
A	X UMBRELLA LIAB / X OCCUR EXCESS LIAB / CLAIMS-MADE DED / RETENTION $	N	N	78199755	7/1/2025	7/1/2026	EACH OCCURRENCE AGGREGATE $	$ 20,000,000 $ 20,000,000 $ XXXXXXX
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	71839067	7/1/2025	7/1/2026	X PER STATUTE / OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
A	PROD-COMPLOPS/CLAIMS MADE RETRO DED EA OCC$10,000	N	N	99510818	7/1/2025	7/1/2026	AGG LMT - $5,000,000 EA OCC LMT - $5,000,00 DED AGG - $50,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

UMBRELLA LIABILITY POLICY IS EXCESS OVER THE COMMERCIAL GENERAL LIABILITY, HIRED AND NON-OWNED AUTOMOBILE LIABILITY, AND EMPLOYERS LIABILITY COVERAGE'S ONLY. CERTIFICATE IS ISSUED AS PROOF OF INSURANCE. GENERAL LIABILITY POLICY INCLUDES ADDITIONAL INSURED STATUS, AS REQUIRED BY WRITTEN CONTRACT AND SUBJECT TO THE TERMS AND CONDITIONS OF THE POLICY.

COVERAGE APPLIES TO: 5200 Tradeport Drive, Memphis, TN 38141

CERTIFICATE HOLDER

19474248
PROOF OF INSURANCE

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE: Joseph M Agnello

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UBS AG
Stamford, 06901 CT
Phone + 1 212 821 30 00
SWIFT UBSWUS33XXX

Letter of Credit Services

Elba Monroig
UBS ZCVF-MOE
Eleven Madison Avenue, 9th Floor
New York, NY 10010
Phone +1 212 821 6752
Fax +1 212 821 6707

www.ubs.com/tef

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PARKWAY
STE 206
RENO, NEVADA 89521

03. December 2025

Amendment to Irrevocable standby-L/C No. WAGA-A09273-1830
dated 16. June 2023
for USD 25,000.00 (United States Dollar twenty-five thousand)
Debtor in the underlying transaction: LIFE SCIENCE LOGISTICS LLC, 3100 OLYMPUS BLVD., SUITE 100, COPPELL, TX 75019

Our above-mentioned undertaking is amended as follows:

THE FOLLOWING ADDRESSES ARE ADDED TO THE LIST OF WAREHOUSES IN THE FIRST PARAGRAPH OF THE LETTER OF CREDIT:

5200 Tradeport Dr, Memphis, TN 38141 and
3530 Brightleaf Lane, Apex, NC 27523

All other terms and conditions remain unchanged.

UBS AG Stamford Branch

Elba Monroig
Associate Director

Ainur Baigamyt
Associate Director

Bond Rider add Address

UBS AG
Stamford, 06901 CT
Phone + 1 212 821 30 00
SWIFT UBSWUS33XXX

Letter of Credit Services

Elba Monroig
UBS ZCVF-MOE
Eleven Madison Avenue, 9th Floor
New York, NY 10010
Phone +1 212 821 6752
Fax +1 212 821 6707

www.ubs.com/tef

Courier service 00204089

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PARKWAY
STE 206
RENO, NEVADA 89521

Attention: CANDY NALLY

03. December 2025

Our reference: WAGA-A09273-1830

Cover letter

Form of undertaking:	Irrevocable standby-L/C (ISP98)
Purpose:	Payment
Amount:	USD 25,000.00
Validity:	15. June 2026

Debtor in the underlying transaction:
LIFE SCIENCE LOGISTICS LLC
3100 OLYMPUS BLVD., SUITE 100
COPPELL, TX 75019

Beneficiary:
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PARKWAY
RENO, NEVADA 89521

Kindly find enclosed the original amendment to our above-mentioned undertaking.

PLEASE MAKE NOTE, OUR NEW MAILING ADDRESS IS NOW
UBS AG, STAMFORD BRANCH
ELEVEN MADISON AVENUE, 9TH FLOOR
NEW YORK, NY 10010
ATTN: LETTER OF CREDIT SERVICES

ALL CORRESPONDENCE INCLUDING DRAWINGS, IF ANY, ARE TO BE PRESENTED TO OUR NEW ADDRESS.

Yours faithfully,

UBS AG Stamford Branch
Valid without signature

Enclosure(s)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG LifeScience Logistics, LLC MDEG License # (if applicable) N/A

Physical Address 5200 Tradeport Drive

City Memphis State TN Zip 38141

Mailing Address (if different from physical address) c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City Middletown State NY Zip 10940

Telephone (845) 544-2482 Website www.lslog.com

Licensing Company Email LSL@slsny.com

Section 2: Personal Information

First Harold Middle Preston Last Fagan II

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or IT[redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Acworth State GA Zip [redacted]

Telephon[redacted] Email HFagan@lslog.com

Are you a citizen of the United States? ☒ Yes No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Alabama		08/97 – 08/01	
Address	City	State	Zip
500 University Boulevard East	Tuscaloosa	AL	35401
Diploma/Degree obtained, if any			
Bachelor of Science, Human Environmental Science			

School Name		From - To (MM/YY – MM/YY)	
Westlake High School		08/93 – 06/97	
Address	City	State	Zip
3300 Middletown Rd	Waldorf	MD	20603
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2021 - Present	[redacted]	Acworth	GA	[redacted]
08/2020 - 03/2021		Acworth	GA	
07/24 – 07/25		Collierville	TN	
01/15 – 08/2020		Collierville	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

LifeScience Logistics®

July 30, 2025

To Whom It May Concern:

I, Harold Fagan II, am the Designated Representative/Responsible Person for the LifeScience Logistics, LLC ("LSL") facility located at 5200 Tradeport Drive, Memphis, TN 38141. My primary residential address is [redacted] I will be flying back and forth to Memphis and staying at a hotel during the week so that I am physically present at the LSL facility during business hours.

If you have any questions or require any additional information, please let us know.

Sincerely,

Harold Fagan II

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
LifeScience Logistics, LLC			07 /25 - Present	
Business Address	**City**		**State**	**Zip**
5200 Tradeport Drive	Memphis		TN	38141
Phone	**Title**		**Number of Employed Hours**	
(205) 396-6164	Director of Commercial Operations		692	

Description of Duties
Lead and execute commercial strategy across national and regional markets, aligning sales, marketing, and client services to drive revenue growth and customer satisfaction, Collaborate with executive leadership to identify and pursue new business opportunities, including RFP responses, strategic partnerships, and market expansion, Manage and mentor a cross-functional team including sales operations, business development, and customer onboarding to ensure seamless execution and accountability.

Business Name			From - To (MM/YY – MM/YY)	
EVERSANA			04/24 - 07/25	
Business Address	**City**		**State**	**Zip**
5650 Challenge Dr	Memphis		TN	38115
Phone	**Title**		**Number of Employed Hours**	
(800) 367-5690	Director of Operations/Plant Manager		2080	

Description of Duties
Directed end-to-end logistics operations for a multi-site pharmaceutical distribution operation with annual operations exceeding $87M, achieving a 15% boost in inventory turnover through, Collaborated with cross-functional teams to enhance operational efficiency and compliance with FDA and healthcare standards.

Business Name			From - To (MM/YY – MM/YY)	
DHL SUPPLY CHAIN			09/21 - 03/24	
Business Address	**City**		**State**	**Zip**
360 Westar Blvd	Westerville OH		OH	43082
Phone	**Title**		**Number of Employed Hours**	
(614)865 8500	Director of Operations		5200	

Description of Duties
Generated over $250M in annual revenue, managing supply chain solutions for premier life sciences clients including Pfizer, Johnson & Johnson, and Roche, Improved SLA compliance to 99%, enhancing service delivery for time-sensitive healthcare products, Reduced distribution costs by $2.5M annually through process improvement, warehouse.

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Harold Preston Fagan II, **certify that as the MDEG Administrator for**

LifeScience Logistics, LLC,

that I (initial that you have read and meet the following requirements):

1. yes Have a high school diploma or its equivalent;
2. yes Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. yes Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. yes Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Harold Preston Fagan II
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/1/25
Date

Board Use Only	Date Received: 12/8/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: LifeScience Logistics, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 5200 Tradeport Drive

City: Memphis State: TN Zip: 38141

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.lslog.com

Licensing Company Email: LSL@slsny.com

Section 2: Personal Information

First: Harold Middle: Preston Last: Fagan II

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Acworth State: GA Zip: [redacted]

Telephon: [redacted] Email: HFagan@lslog.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Alabama		08/97 – 08/01	
Address	City	State	Zip
500 University Boulevard East	Tuscaloosa	AL	35401
Diploma/Degree obtained, if any			
Bachelor of Science, Human Environmental Science			

School Name		From - To (MM/YY – MM/YY)	
Westlake High School		09/95 – 06/97	
Address	City	State	Zip
3300 Middletown Rd	Waldorf	Md	20603
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2021 - Present	[redacted]	Acworth	GA	[redacted]
08/2020 - 03/2021		Acworth	GA	
07/2024 - 07-25		Collierville	TN	
01/2015 - 08/2020		Collierville	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
LifeScience Logistics, LLC		07 /2025 - Present	
Business Address	**City**	**State**	**Zip**
5200 Tradeport Drive	Memphis	TN	38141
Phone	**Title**	**Number of Employed Hours**	
(469) 844-3699	Director of Commercial Operations	692	

Description of Duties

Lead and execute commercial strategy across national and regional markets, aligning sales, marketing, and client services to drive revenue growth and customer satisfaction, Collaborate with executive leadership to identify and pursue new business opportunities, including RFP responses, strategic partnerships, and market expansion, Manage and mentor a cross-functional team including sales operations, business development, and customer onboarding to ensure seamless execution and accountability.

Business Name		From - To (MM/YY – MM/YY)	
EVERSANA		04/24 - 07/25	
Business Address	**City**	**State**	**Zip**
5650 Challenge Dr	Memphis	TN	38115
Phone	**Title**	**Number of Employed Hours**	
(800) 367-5690	Director of Operations/Plant Manager	2080	

Description of Duties

Directed end-to-end logistics operations for a multi-site pharmaceutical distribution operation with annual operations exceeding $87M, achieving a 15% boost in inventory turnover through, Collaborated with cross-functional teams to enhance operational efficiency and compliance with FDA and healthcare standards.

Business Name		From - To (MM/YY – MM/YY)	
DHL SUPPLY CHAIN		10 /21 - 03/24	
Business Address	**City**	**State**	**Zip**
360 Westar Blvd	Westerville	OH	43082
Phone	**Title**	**Number of Employed Hours**	
(614) 865-8500	Director of Operations	5200	

Description of Duties

Generated over $250M in annual revenue, managing supply chain solutions for premier life sciences clients including Pfizer, Johnson & Johnson, and Roche, Improved SLA compliance to 99%, enhancing service delivery for time-sensitive healthcare products, Reduced distribution costs by $2.5M annually through process improvement, warehouse.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Harold Preston Fagan II, **certify that as the designated representative for**

LifeScience Logistics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. yes I am at least 21 years of age;
3. yes I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. yes I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. yes I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. yes I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. yes I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Harold Preston Fagan II

Print Name (First, Last)

HPF

Original Signature (electronic, copies or stamps not accepted)

10/1/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Harold Preston Fagan II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Mississippi, ss. County of De Soto

I, Harold Fagan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Harold Preston Fagan II

10/6/2025

Date

Subscribed and Sworn to before me this 6th day of Oct 2025.

Notary Public Signature

★ STATE OF MISSISSIPPI ★
MILLIE POWERS, NOTARY PUBLIC
DE SOTO COUNTY
MY COMMISSION EXPIRES JUNE 24, 2029
COMMISSION NUMBER 291644
(Seal)

First Name	Last Name
Harold	Fagan
Robert	Douglas
Aspen	Moore
Chris	Cowan
Jesus	Estrada
Erika	Prewitt
Walter	Booker
Kennedy	Miller
Stephanie	Macias
Carla	Tillman
Samitrius	Bailey
Cody	Hines
Jarvis	Shelton
Maricela	Macias
Jonaymis	Bustamant
April	Crawford
Christen	Mitchell

Employee List

TMC Current Active Employees (15 OCT 2025)

Position	Name
Director of Ops	Harold Fagan
Supervisor (Inbound/IC)	Robert Douglass
Warehouse Lead	Aspen Moore
Account Manager	Bryant Jones
WMS Analyst	Derek Mosley

20 OCT 2025 – NEO

Position	Name
Supervisor (Outbound)	Shawn Patterson
Inventory Control Specialist	Kameron Millen
Associate I	DeVoniele Turner
Receptionist	Savannah McGruder
HR Generalist	Chris Ables
OD Trainer	Emily Coward

17 NOV 2025 - NEO

Position	Name
QA Supervisor	Krystal Ejimofor

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Novartis Manufacturing LLC

Physical Address: 1890 Rutherford Rd., Suite 200

City: Carlsbad State: CA Zip: 92008

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: _____ Website: www.Novartis.com

Name of Designated Representative (DR): Dominic Ramirez-Lopez

Licensing Company Email: dominic.ramirez-lopez@novartis.com DR Email: dominic.ramirez-lopez@novartis.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☑ Others: Iniectables	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Clinics		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded ~~Corporation or~~ Company (Limited Liability Company)

State of Incorporation/Organization: Delaware

Parent Company (if any): Novartis Finance Corporation

~~Corporation~~/Organization Name: Novartis Manufacturing LLC

Mailing Address: 1890 Rutherford Rd., Suite 200

City: Carlsbad State: CA Zip: 92008

Telephone: 760-602-1600 ext 61600 Email: dominic.ramirez-lopez@novartis.com

Contact Person Name: Dominic Ramirez-Lopez

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Pending - See Attachment A		
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment B		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment C		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment E		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8) N/A				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Novartis Manufacturing LLC

Facility Name

Dominic Ramirez-Lopez

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

03 Sep 2025

Date

Board Use Only	Date Received: 9/5/25	Amount: $1000 CK 2850

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Novartis Manufacturing LLC**

CSVExcel

Filter: 1890

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Novartis Manufacturing LLC	3013510604	048687485	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK;	1890 Rutherford Road, Suite 200, Carlsbad, California (CA) 92008, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Tuesday, Jan 6, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Attachment C

LLC Information

Novartis Manufacturing LLC

John McKenna
President

Eduard Marti
Treasurer

Jaime Huertas
Secretary

Parent Company

Novartis Finance Corporation
One Health Plaza,
East Hanover, New Jersey 07936

Percent Ownership: 100%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NOVARTIS MANUFACTURING LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NOVARTIS MANUFACTURING LLC" WAS FORMED ON THE TWENTY-SEVENTH DAY OF MARCH, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7915184 8300

SR# 20251134962

Authentication: 203214031

Date: 03-19-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DRUG MANUFACTURING LICENSE

Novartis Manufacturing LLC
1890 Rutherford Rd Ste 200
Carlsbad, CA 92008

LICENSE NUMBER: 126242
EXPIRATION DATE: 11/5/2027

The person named herein is licensed to manufacture drugs through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

OSH 01 02308

Printed: 11/12/2025

Docusign Envelope ID: E7DE4F41-F0C3-410D-89E9-06F89E560E41

Liberty Mutual SURETY

BOND RIDER

To be attached to and form a part of :

Bond No.: 019089033

Cross Ref Bond No.:

Type of Bond: Pharmaceutical Wholesaler Surety Bond

Dated effective: November 10, 2023

Executed by: NOVARTIS MANUFACTURING LLC

, as Principal,

And by: LIBERTY MUTUAL INSURANCE COMPANY , as Surety,

In favor of: NEVADA STATE BOARD OF PHARMACY

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to:

Changing: Adding additional service address

From: 8520 Challenger Drive, Indianapolis, IN 46241

To: 8520 Challenger Drive, Indianapolis, IN 46241 and
1890 Rutherford Road, Suite 200, Carlsbad, CA 92008

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective: August 20, 2025

Signed and Sealed on: August 15, 2025

Principal Name: NOVARTIS MANUFACTURING LLC

Signed by:
By: Jaime Huertas
00BB3CFBAF29433...
Jaime Huertas, Secretary

Surety Name: LIBERTY MUTUAL INSURANCE COMPANY

DocuSigned by:
By: Elizabeth P. Cervini
21BE4801DCCA48...
Elizabeth P. Cervini, Attorney-in-Fact

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS
Seal No. 5865

Agency Name: R&P Surety, LLC

Agency Address: 595 E. Swedesford Road, Suite 350, Wayne, PA 19087

Docusign Envelope ID: E7DE4F41-F0C3-410D-89E9-06F89E560E41

Liberty Mutual. SURETY

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8213110- 019008**

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint Nevin L. Beyer, Jonathan F. Black, Denise M. Bruno, Julia R. Burnet, Elizabeth P. Cervini, James M. DiSciullo, Stephanie S. Helmig, Melissa J. Hinde, Christine M. Hrusovsky, David A. Johnson, Elizabeth B. Pendleton, Michelle L. Richards, David C. Rosenberg, Harry C. Rosenberg, John E. Rosenberg, Matthew J. Rosenberg

all of the city of Wayne state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 10th day of February 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 10th day of February, 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 15th day of August, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Novartis Manufacturing LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 1890 Rutherford Rd., Suite 200

City: Carlsbad State: CA Zip: 92008

Mailing Address (if different from physical address): Same as physical

City: State: Zip:

Telephone: 760-602-1600 ext 6160 Website: www.Novartis.com

Licensing Company Email: dominic.ramirez-lopez@novartis.com

Section 2: Personal Information

First: Dominic Middle: Last: Ramirez-Lopez

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 1890 Rutherford Rd., Suite 200

City: Carlsbad State: CA Zip: 92008

Telephon[redacted] Email: dominic.ramirez-lopez@novartis.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	☐	☑
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	☐	☐

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, Riverside		09/05 - 07/10	
Address	**City**	**State**	**Zip**
900 University Ave	Riverside	CA	92521
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE, BIOLOGICAL SCIENCES – Emphasis in Medical Biology			

School Name		From - To (MM/YY – MM/YY)	
Granite Hills High School		06/01 - 06/05	
Address	**City**	**State**	**Zip**
22900 Esaws Ave	Apple Valley	CA	92307
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2022 - Present	[redacted]	Oceanside	CA	[redacted]
03/2019-2022		Cary	IL	
12/18-03/19		Libertyville	IL	
11/15-12/18		Rancho Santa Margarita	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY –MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Novartis Manufacturing LLC			05/24 - Present	
Business Address		**City**	**State**	**Zip**
1890 Rutherford Rd., Suite 200		Carlsbad	A	92008
Phone	**Title**		**Number of Employed Hours**	
619-613-1763	Site Head, Carlsbad		Approx. 3,000 hours	
Description of Duties				
General Manager of site operations functions. Senior leader of the Carlsbad facility.				

Business Name			From - To (MM/YY – MM/YY)	
Novartis Pharmaceuticals Corporation			04/22 - 05/24	
Business Address		**City**	**State**	**Zip**
1 Health Plz		East Hanover	NJ	07936
Phone	**Title**		**Number of Employed Hours**	
862-778-8300	Head of Preclinical Manufacturing, TR&D		Approx. 4,000 hours	
Description of Duties				
Head of Preclinical Manufacturing, TR&D				

Business Name			From - To (MM/Y – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Dominic Ramirez-Lopez **, certify that as the designated representative for**

Novartis Manufacturing LLC ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DRL I am at least 21 years of age;
3. DRL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity relatedto the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DRL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DRL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DRL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DRL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dominic Ramirez-Lopez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05Sep2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dominic Ramirez-Lopez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03Sep2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Diego

I, Dominic Miguel Ramirez Lopez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04 Sep 2025

Date

Subscribed and Sworn to before me this 04 day of September, 2025

Notary Public Signature

LYSANDER CALIGUIRAN FABIAN
Notary Public - California
San Diego County
Commission # 2507001
My Comm. Expires Dec 16, 2028

(Seal)

CALIFORNIA NOTARIAL CERTIFICATE
(JURAT)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of San Diego

Subscribed and sworn to (or affirmed) before me on this 04 day of September, 20 25, by Dominic Miguel Ramirez Lopez, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____. (Seal)

LYSANDER CALIGUIRAN FABIAN
Notary Public - California
San Diego County
Commission # 2507001
My Comm. Expires Dec 16, 2028

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Attachment F

List of Employees

Luke Silvey
Lexi Roros
Jessica Kukar
Martha Sosa
David Hwang
Tiarra Johnson
Parth Patel
Patrick Piszczatowski
Joseph Ponce
Daniel Scannell
Jonathan Fausto
Cecil Don
Carter Jaynes
Robin Connally
Mario Merino
Roderick Freeman
Dominic Ramirez-Lopez

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Philips Image Guided Therapy Corporation

Physical Address: 3721 Valley Center Drive, Suite 500

City: San Diego State: CA Zip: 92130

Mailing Address (if different from physical address): Same as physical address.

City: _____ State: _____ Zip: _____

Telephone: 858-720-4020 Website: www.usa.philips.com/healthcare

Name of Designated Representative (DR): David Horton

Licensing Company Email: statelicense@philips.com DR Email: statelicense@philips.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer (Virtual)
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Philips Image Guided Therapy Corporation
Address: Coyol Free Zone and Business Park, Building B37 City: Coyol Alajuela State: Costa Rica Zip: N/A
Name: Philips Image Guided Therapy Corporation
Address: 2451 Mercantile Drive City: Rancho Cordova State: CA Zip: 95670
Name: N/A
Address: City: State: Zip:
Name:
Address: City: State: Zip:

N/A

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Philips Holding USA, Inc.
Corporation/Organization Name: Philips Image Guided Therapy Corporation
Mailing Address: 3721 Valley Center Drive, Suite 500
City: San Diego State: CA Zip: 92130
Telephone: 858-720-4020 Email: statelicense@philips.com
Contact Person Name: David Horton

N/A

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Philips Image Guided Therapy Corporation

Facility Name

David Horton

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/8/25

Date

Board Use Only	Date Received: 12/11/25	Amount: $1000 ck 2081

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
N/A 1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment B		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Attachment C	✓			
• **List of all corporation shareholders and their percent ownership.** N/A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment E		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - wholly owned by parent company		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

FDA

FDA Home | Medical Devices | Databases

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
Volcano Corporation
Business Trade Name:
Philips Image Guided Therapy Corporation

3721 Valley Centre Dr Ste 500
San Diego, CA 92130
Registration Number: 3008363989
FEI Number*: 3008363989
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types
Please Review Listings For Further Information
Date Of Registration Status: 2025

Owner/Operator:
Philips Medical Systems International BV
Veenpluis 6
Best, NL 5684PC

Owner/Operator Number: 2939520

Official Correspondent:
Megan Oler
Philips
9965 Federal Drive
Colorado Springs, CO 80921
Phone: 719-4472592

*Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2939520&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn

Page Last Updated: 01/06/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

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Attachment C

Corporation Information

Philips Image Guided Therapy Corporation
3721 Valley Center Drive, Suite 500
San Diego, CA 92130

Parent Company:

Philips Holding USA, Inc.
6501 Living Place, Pittsburgh, PA 15206
% Ownership: 100

Corporate Officers:

Stacy Beske Radford
President

Paul Cavanaugh
Vice President

Joseph E. Innamorati
Vice President and Secretary

Prashan Gomez
Vice President and Treasurer

Irma I. Gomez
Assistant Secretary

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHILIPS IMAGE GUIDED THERAPY CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SEVENTH DAY OF JANUARY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHILIPS IMAGE GUIDED THERAPY CORPORATION" WAS INCORPORATED ON THE TWELFTH DAY OF JANUARY, A.D. 2000.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3155105 8300

SR# 20260309112

Authentication: 202921818

Date: 01-27-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Philips Image Guided Therapy Corporation
3721 Valley Center Dr Ste 500
San Diego, CA 92130

LICENSE NUMBER: 111123
EXPIRATION DATE: 2/19/2027

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 12/23/2024

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
12/28/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, LLC.
1166 Avenue of the Americas
New York, NY 10036
Attn: NewYork.Certs@marsh.com Fax: 212-948-0500

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : National Union Fire Insurance Company of Pittsburgh,	19445
INSURER B : Safety National Casualty Corp.	15105
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Philips North America LLC
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

COVERAGES **CERTIFICATE NUMBER:** NYC-011250033-22 **REVISION NUMBER:** 7

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			536-18-48	12/31/2024	12/31/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ $ $ $ $ $ $	2,000,000 3,000,000 10,000 2,000,000 5,000,000 5,000,000
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA6675481	12/31/2024	12/31/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ $ $ $ $	2,000,000
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			041233800	12/31/2024	12/31/2025	EACH OCCURRENCE AGGREGATE $	$ $ $	5,000,000 5,000,000
B B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N N/A If yes, describe under DESCRIPTION OF OPERATIONS below			LDS4047559 (AOS) PS4047560 (WI)	12/31/2024 12/31/2024	12/31/2025 12/31/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $	 2,000,000 2,000,000 2,000,000
A	CYBER LIABILITY			39325976 'Subject to a policy deductible'	12/31/2024	12/31/2025	Per Occurrence Limit: Aggregate Limit:		10,000,000 10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of coverage
This certificate applies to all employees of the named insured's who are applying for vendor access at medical facilities. All operations in the United States and Canada (see attached). The Certificate Holder named below is Additional Insured where required by written contract or agreement under the Vendors' Broad Form referenced on the attached. Coverage Includes Host Liquor Liability.

CERTIFICATE HOLDER
Philips North America LLC
(See additional page for other Insureds)
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN101736188

LOC #: New York

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA, LLC.	Philips North America LLC (See additional page for other Insureds) 222 Jacobs Street, 3rd Floor, Cambridge, MA 02141
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Holter Direct, LLC
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Angioscore LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA, LLC.	Philips North America LLC (See additional page for other Insureds) 222 Jacobs Street, 3rd Floor, Cambridge, MA 02141
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Remote Diagnostics Technologies LLC
Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
*See attached list of principal addresses, as
Address of Applicant/Principal
PRINCIPAL, and Western Surety Company, a
Surety Company
corporation organized under the laws of the state of South Dakota
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
151 N Franklin Street Chicago, IL 60606 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact

print name

Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness April D. Perez

Countersigned by:

N/A

Nevada Resident Agent

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2021

ASSETS

Bonds	$	1,940,298,870
Stocks		19,721,943
Cash, cash equivalents, and short-term investments		32,146,891
Receivables for securities		140,000
Investment income due and accrued		17,433,547
Premiums and considerations		54,366,110
Amounts recoverable from reinsurers		3,204,634
Current federal and foreign income tax recoverable and interest thereon		-
Net deferred tax asset		14,565,007
Receivable from parent, subsidiaries, and affiliates		14,891,869
Other assets		1,037
Total Assets	$	2,096,769,908

LIABILITIES AND SURPLUS

Losses	$	214,859,103
Loss adjustment expense		48,667,258
Commissions payable, contingent commissions and other similar charges		10,885,216
Other expenses (excluding taxes, license and fees		-
Taxes, License and fees (excluding federal and foreign income taxes)		2,781,662
Federal and foreign income taxes payable		300,285
Unearned premiums		263,317,295
Advance premiums		6,618,279
Ceded reinsurance premiums payable (net of ceding commissions)		5,081,348
Amounts withheld or retained by company for account of other		10,237,011
Provision for reinsurance		6,261,560
Payable to parent, subsidiaries and affiliates		7,170
Payable on security transactions		35,226
Other liabilities		155,189
Total Liabilities	$	569,206,602

Surplus Account:			
Common stock	$ 4,000,000		
Gross paid in and contributed surplus	286,896,195		
Unassigned funds	1,236,667,111		
Surplus as regards policyholders		$	1,527,563,306
Total Liabilities and Capital		$	2,096,769,908

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

APPLICANT/PRINCIPALS:

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Paul Cavanaugh

Authorized Representative - [redacted] Paul Cavanaugh

Witness

Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman

Witness

Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LLC LIMITED LIABILITY SEAL 2007 CALIFORNIA COMPANY

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY SEAL 1987 DELAWARE COMPANY

PHILIPS ULTRASOUND LLC LIMITED LIABILITY SEAL 1973 WASHINGTON COMPANY

SPECTRANETICS LLC LIMITED LIABILITY SEAL 1988 DELAWARE COMPANY

PHILIPS IMAGE GUIDED THERAPY SEAL 2000

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Kristin S. Bender

, Individually

of Morristown, New Jersey, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

Surety Bond Number: 30185503
Principal: See attached list of principals
Obligee: State of Nevada and Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat

Paul T. Bruflat, Vice President

WESTERN SURETY COMPANY CORPORATE SEAL SOUTH DAKOTA

State of South Dakota }
County of Minnehaha } ss

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT NOTARY PUBLIC SOUTH DAKOTA SEAL SEAL

M. Bent

M. Bent, Notary Public

CERTIFICATE

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 21 day of April, 2023.

WESTERN SURETY COMPANY CORPORATE SEAL SOUTH DAKOTA

WESTERN SURETY COMPANY

L. Nelson

L. Nelson, Assistant Secretary

Form F4280-2-2021

Authorizing By-Law

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Philips Image Guided Therapy Corporation MDEG License # (if applicable) N/A

Physical Address 3721 Valley Center Drive, Suite 500

City San Diego State CA Zip 92130

Mailing Address (if different from physical address) Same as physical address.

City _____ State _____ Zip _____

Telephone 858-720-4020 Website www.usa.philips.com/healthcare

Licensing Company Email statelicense@philips.com

Section 2: Personal Information

First David Middle Michael Last Horton

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 3721 Valley Center Drive, Suite 500

City San Diego State CA Zip 92130

Telephone [redacted] Email statelicense@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Diego State University			
Address	**City**	**State**	**Zip**
5500 Campanile Dr	San Diego	CA	92182
Diploma/Degree obtained, if any			
M.S. Regulatory Affairs			
School Name		**From - To (MM/YY – MM/YY)**	
Brigham Young University			
Address	**City**	**State**	**Zip**
212 Hinckley Center	Provo	UT	84602
Diploma/Degree obtained, if any			
B.B.A., Business Administration and Management, General & Engineering			
School Name		**From - To (MM/YY – MM/YY)**	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2024 - Present	[redacted]	San Diego	CA	[redacted]
- 9/2024		Erie	CO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Philips Image Guided Therapy Corporation			1/2024 - Present	
Business Address	**City**		**State**	**Zip**
3721 Valley Center Drive, Suite 500	San Diego		CA	92130
Phone	**Title**		**Number of Employed Hours**	
858-720-4020	Head of Regulatory Affairs, IGTD-CV		40 hours per week	
Description of Duties				
Lead/Manager Regulatory department for Philips Image Guided Therapy Corporation Vascular and Device business.				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			12/2006 - 6/2023	
Business Address	**City**		**State**	**Zip**
6135 Gunbarrel Ave	Boulder		CO	80301
Phone	**Title**		**Number of Employed Hours**	
(800) 635-5267	Director of Regulatory Affairs		40 hours per week	
Description of Duties				
Department staffing, organization structure, budget, and people development since 2010 including managers with reports. Represent function at leadership meetings. Primary point of contact for FDA and notified bodies during premarket submissions. Responsible for global regulatory strategies, submissions, and department QMS procedures Monitor and report on global regulatory changes, including standards (ISO, IEC), laws, and regulations.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name N/A			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, David Horton, **certify that as the MDEG Administrator for**

Philips Image Guided Therapy Corporation,

that I (initial that you have read and meet the following requirements):

1. DM Have a high school diploma or its equivalent;
2. DM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Horton
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/8/25
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Philips Image Guided Therapy Corporation

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 3721 Valley Center Drive, Suite 500

City: San Diego State: CA Zip: 92130

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 858-720-4020 Website: www.usa.philips.com/healthcare

Licensing Company Email: statelicense@philips.com

Section 2: Personal Information

First: David Middle: Michael Last: Horton

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 3721 Valley Center Drive, Suite 500

City: San Diego State: CA Zi[redacted]

Telephon[redacted] Email: statelicense@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Diego State University		09/05 - 05/09	
Address	**City**	**State**	**Zip**
5500 Campanile Dr.	San Diego	CA	92182
Diploma/Degree obtained, if any			
M.S. Regulatory Affairs			

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		05/2002 - 05/2005	
Address	**City**	**State**	**Zip**
212 Hinckley Center	Provo	UT	84602
Diploma/Degree obtained, if any			
B.B.A., Business Administration and Management, General & Engineering			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2024 - Present	[redacted]	San Diego	CA	[redacted]
8/2007- 9/2024		Erie	CO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Philips Image Guided Therapy Corporation			1/2024 - Present	
Business Address		**City**	**State**	**Zip**
3721 Valley Center Drive, Suite 500		San Diego	CA	92130
Phone	**Title**		**Number of Employed Hours**	
858-720-4020	Head of Regulatory Affairs, IGTD-CV		40 hours per week	
Description of Duties				
Lead/Manager Regulatory department for Philips Image Guided Therapy Corporation Vascular and Device business.				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			12/2006 - 6/2023	
Business Address		**City**	**State**	**Zip**
6135 Gunbarrel Ave		Boulder	CO	80301
Phone	**Title**		**Number of Employed Hours**	
(800) 635-5267	Director of Regulatory Affairs		40 hours per week	
Description of Duties				
Department staffing, organization structure, budget, and people development since 2010 including managers with reports. Represent function at leadership meetings. Primary point of contact for FDA and notified bodies during premarket submissions. Responsible for global regulatory strategies, submissions, and department QMS procedures Monitor and report on global regulatory changes, including standards (ISO, IEC), laws, and regulations.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name N/A			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

I, David Horton **, certify that as the designated representative for**

Philips Image Guided Therapy Corporation ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, ~~prescription drugs~~. Medical devices
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Horton

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/8/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Horton

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/5/25

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Diego

I, David Horton, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/5/25

Date

Subscribed and Sworn to before me this 5 day of December.

Notary Public Signature

See Attached Certificate

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of San Diego

Subscribed and sworn to (or affirmed) before me on this 5 day of December, 20__, by David Horton,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

JOSEPH KHOURY
Notary Public - California
San Diego County
Commission # 2523389
My Comm. Expires Jul 5, 2029

(Seal)

Signature J Khoury

Name
Alexander Tieger
Alfred McBride
Alma Garde
Alma Mohr
Alyssa Brianne Silva
Andres Fojaco Gomez
Andrew Belandres
Andrew Tochterman
Angelica Andrade
Angie Garma
Anita Joslyn
Annie Lam
Asana Pebdani
Ashlee Gora
Benjy Gonzalez
Blake Cornell
Bob Shokoohi
Brandon Scanlon
Brian Park
Brittany Garcia
Bryan Gaudreau
Buna Roesch
Caleigh Crowell
Carla Campos Jimenez
Carlos Ayala
Catherine Perez
Courtney Ruth
Cynthia Feliciano
Daniel Exum
Daniel Kim
David Chalyan
David Kendrick
Denysse Castaneda
Derek Rissman
Diane Amin
Donald Ellis
Eddie Castro
Eric Henderson
Erin Cerra
Felix Torres
Gail Calhoun
Gavin Wormull
Gayle Cooper

Grace Yakutis
Gus Patton
Hector Monta
Herminio Armas Macias
Celine Li
Jacob Rouw
James Cezo
James Radden
Jeff Scott
Jeffrey Brown
Jeffrey Reyes
Jennifer Foster
Jiantao Lu
Drew Hoffman
John Tanayan
Jonathan Batiller
Jonathan Delos Santos
Frank Garcia
Jose Navarro
Jose Valencia
Joseph Lewis
Joseph Woods
Juli Cronan
Julie Lyon
Justin Bronaugh
Kathy Zhang
Kellen Moulton
Kelly Mobley
Keniya Coleman
Kevin Milner
Kevin Wyrwich
Kurt Riedel
Kyla Manawatao
Lauren Fossile
Larry Cull
Leilani Taylor
Letitia Mwangi
Leyla Yamin
Lina Wang
Lisa Rothemund
Lorenzo Caminiti
Lou Pendley
Mahina Saucedo
Maria Heiling

Maria Serrato
Marisela Barrientos
Mark Lyell
Mark Richardson
Mark Whitehead
Megan Brenner
Megan Thomas
Megan Wilkie
Melisa Friday
Melissa Muto
Melody Muehlbauer
Mercedita Bernal
Meredith Boutelle
Micah Tattao
Michael Blaney
Michael Choi
Michael McMickle
Michelle Ditsch
Miguel Altuna
Miranda Taylor
Miranda Toledo
Natalie Haas
Nikhil Rajguru
Pankaj Jagasia
Patrick Kozina
Paul Khait
Pradeep Baral
Rabindra Parajuli
Ralph Joliuz Aglipay
Ramiro Reyes
Rand Daoud
Ravid Touth
Rebecca Jenkins
Regina Edenburgh
Rey Halili
Robert Crespin
Robert Klepacz
Rohan Sen
Roshan Yohannan
Ryan MacFarland
Ryo Huntamer
Samin Khan
Sara Chen
Sarah Pfannenstiel

Booma Narasimhan
Sayli Kadambande
Scott Walker
Shannon Mohanty
Stephanie Mastacouris
Steven Parker
Steve Zizzo
Stijn Op de Beeck
Stuart Long
Suneethi Gudapati
Sunny Spencer
Syed Alam
Michelle Lange
Tao Wu
Thinh Nguyen
Veronica Cheung
Victor Gonzalez
Vijaya Lakshmi Kandi
Vincent Rosas
Waheed Abdul
Bill Abboud
Kelly Luo
Xiaoyang Cheng
Yanay DiRocco
Mary Gao
Ziggy Fan

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02198	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Renaissance Lakewood, LLC

Physical Address: 1200 Paco Way

City: Lakewood State: NJ Zip: 08701

Mailing Address (if different from physical address): 1200 Paco Way

City: Lakewood State: New Jersey Zip: 08701

Telephone: (732) 367-9000 Website: www.renpharm.com

Name of Designated Representative (DR): Jeffrey Higginson

Licensing Company Email: julie.simon@renpharm.com DR Email: Jeffrey.Higginson@renpharm.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☒ Controlled Substances	☐ Repacker
☐ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Renaissance SSP Holdings, Inc.

Corporation/Organization Name: Renaissance Lakewood, LLC

Mailing Address: 1200 Paco Way

City: Lakewood State: New Jersey Zip: 08701

Telephone: (732) 367-9000 Email: julie.simon@renpharm.com

Contact Person Name: Robert Harrer

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **"Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing "Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Renaissance Lakewood, LLC
Facility Name

Julie Simon
Print Name of Authorized Person Submitting Application

Julie Simon
Original signature of Authorized Person (copies or stamps not accepted)

Nov. 10, 2025
Date

Board Use Only	Date Received: 12/3/25	Amount: $1000 CK 4908

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **RENAISSANCE LAKEWOOD LLC**

CSVExcel

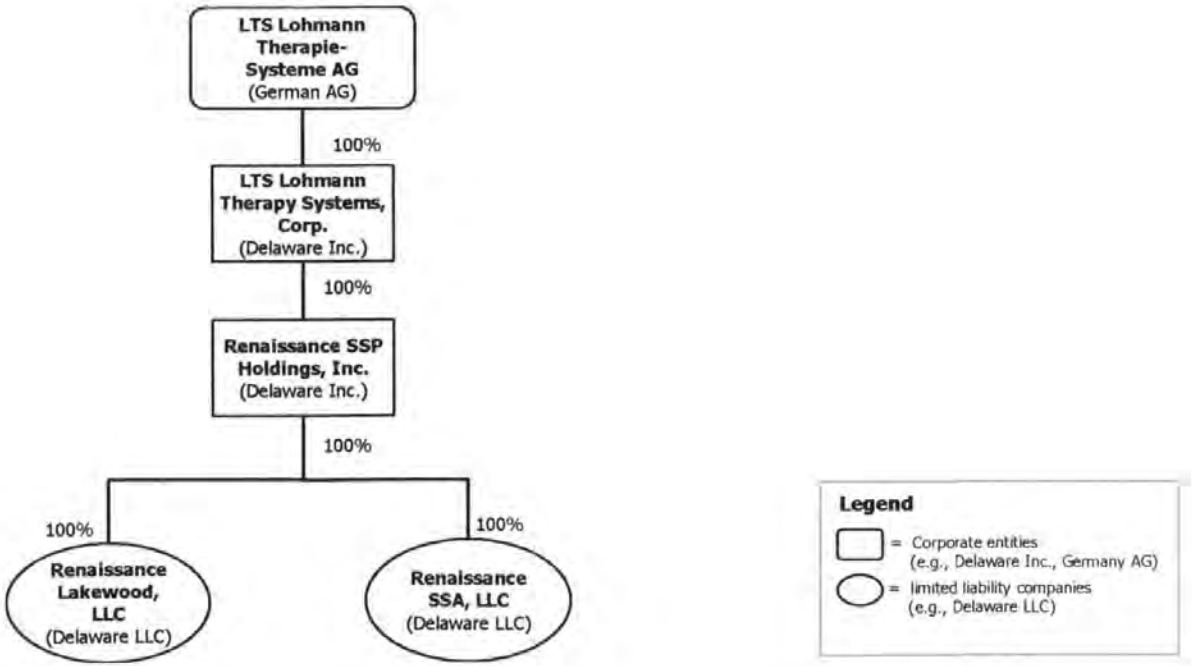
Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Renaissance Lakewood LLC	2242829	077744035	ANALYSIS; LABEL; MANUFACTURE; PACK;	1200 Paco Way, Lakewood, New Jersey (NJ) 08701, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Thursday, Dec 4, 2025

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Project Rose – Post-Closing Structure Chart



(1) For each of Renaissance SSP Holdings, Inc., Renaissance Lakewood, LLC and Renaissance SSA, LLC, the following individuals will be officers: Serge Maltais (President); Robert Harrer (Treasurer); and Julie Simon (Secretary).

(2) The following individuals make up (i) the board of directors of Renaissance SSP Holdings, Inc., (ii) Renaissance Lakewood, LLC's board of managers, and (iii) Renaissance SSA, LLC's board of managers: Bas van Buijtenen, Ulrich Sielaff and Claudia Schaefer.

Renaissance

DESCRIPTION OF OPERATIONS

Renaissance Lakewood, LLC ("Renaissance") is a leading contract development and manufacturing organization located in Lakewood, NJ. Renaissance specializes in manufacturing prescription drugs. At no time does Renaissance own any of their client's finished goods, nor does Renaissance invoice or sell products on behalf of their manufacturing clients.

COMPANY INFORMATION

Renaissance Lakewood, LLC
1200 Paco Way
Lakewood, NJ 08701
Phone: (732) 367-9000
Tax ID: 22-3840741
FDA Establishment Identifier: 2242829
DEA Registration: RD0281383

Renaissance

Company Information

Renaissance Lakewood, LLC
1200 Paco Way
Lakewood, NJ 08701
732-367-9000
www.renpharm.com
Julie.simon@renpharm.com

FEIN:22-3840741
State of Formation: Delaware
Date Incorporated: 12/19/1996

Ownership Information

Renaissance Lakewood, LLC is 100% owned by Renaissance SSP Holdings, Inc.

Parent Company Address: 1200 Paco Way Lakewood, NJ 08701
Parent Company Phone: (732) 730-2720
Parent Company FEIN: 80-0824524

Officer List

Serge Maltais, President and General Manager
Business Address: 1200 Paco Way Lakewood, NJ 08701
Business Phone: (732) 730-2780

Robert Harrer, Chief Financial Officer and Treasurer
Business Address: 1200 Paco Way Lakewood, NJ 08701
Business Phone: (732) 730-3230

Julie Simon, Corporate Secretary and Vice President
Business Address: 1215 Paco Way, Lakewood, NJ 08701
Business Phone: (216) 551-7979

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RENAISSANCE LAKEWOOD, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3452098 8300

SR# 20250108624

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202678588

Date: 01-13-25

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0022827

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written noticeprior to the change of the address of such new location and the name and address of the individual to be in charge thereof.A fee of $20.00 shall accompanying such notification."

Registered as: ☑ Manufacturer ☑ Distributor which conducts business at the following locations:

745 AIRPORT RD LAKEWOOD, NJ 08701

1215 PACO WAY LAKEWOOD, NJ 08701

Reg. No.:
5002900

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

ISSUED PURSUANT TO:
N.J.S.A. 24:6B
EXPIRES: January 31, 2027

Establishment Copy

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0281383	04-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5,L	MANUFACTURER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0281383	04-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5,L1	MANUFACTURER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

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RD0281383	04-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N,4,5,L	MANUFACTURER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
7285 9801 7370 7366 8112 8113 2270 7360 7365

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0360545	04-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N,4	IMPORTER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0360545	04-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N,4	IMPORTER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

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RD0360545	04-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3N,4	IMPORTER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2765 2737 7285 2884

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0336025	04-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	EXPORTER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0336025	04-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	EXPORTER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

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Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0336025	04-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	EXPORTER	03-05-2025

RENAISSANCE LAKEWOOD, LLC
1200 PACO WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
9801 9064 7285 2737 9100 2765 2884 2280 2270

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/28/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. St. Louis MO Office 4220 Duncan Avenue Suite 401 St Louis MO 63110 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE		NAIC #
Renaissance Lakewood, LLC 1200 Paco Way Lakewood NJ 08701 USA	INSURER A:	Columbia Casualty Company	31127
	INSURER B:	National Fire Ins. Co. of Hartford	20478
	INSURER C:	Valley Forge Insurance Co	20508
	INSURER D:	The Continental Insurance Company	35289
	INSURER E:		
	INSURER F:		

COVERAGES **CERTIFICATE NUMBER:** 570113885902 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			6046365660	06/29/2025	06/29/2026	EACH OCCURRENCE	$1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$15,000
							PERSONAL & ADV INJURY	$1,000,000
							GENERAL AGGREGATE	$2,000,000
							PRODUCTS - COMP/OP AGG	Excluded
C	AUTOMOBILE LIABILITY [X] ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			6046365626	06/29/2025	06/29/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
							BODILY INJURY (Per person)	
							BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
							Comp/Coll Deductible	$1,000
D	[X] UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $10,000			6046365674	06/29/2025	06/29/2026	EACH OCCURRENCE	$5,000,000
							AGGREGATE	$5,000,000
							Prod/COpns Agg	Excluded
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			6046365643	06/29/2025	06/29/2026	[X] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000
A	Products Liability			ADT7039555441 Claims Made	06/29/2025	06/29/2026	Each Claim Aggregate Ded Each Event	$10,000,000 $10,000,000 $50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Products Liability Retro Date: 06/23/2000.

CERTIFICATE HOLDER

Two Labs Pharma Services
6832 Collingwood Drive
Westerville OH 43082 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

Holder Identifier :

Certificate No : 570113885902

000000 03 03 024279 078021 P

©1988-2015 ACORD CORPORATION. All rights reserved.

Certificate No: 570113885902

AON

Two Labs Pharma Services
6832 Collingwood Drive
Westerville OH 43082 USA

Saturday, June 28, 2025

To whom it may concern:

Following a concentrated effort to reduce our environmental footprint and provide timely certificate delivery, Aon will begin delivering our Certificates of Insurance electronically in PDF format.

Please utilize one of the following methods to ensure you will receive the electronic copy of your Certificate (Certificate No: **570113885902**) for future renewals:

- Visit aon.com/e-cert; or
- Utilize the QR Code below to enter/validate your information.

If your email address has changed or will be changing in the future, or you no longer require this certificate, please let us know using one of the methods above.

Thank you for your cooperation and willingness to help us reduce our impact to the environment.

Aon Risk Services
5801 Postal Road
PO Box 818037
Cleveland, Ohio 44181-9600

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBIX7712

Application/License No. _____

RENAISSANCE LAKEWOOD, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1200 Paco Way Lakewood, NJ 08701 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of November, 2022.

APPLICANT/PRINCIPAL
RENAISSANCE LAKEWOOD, LLC

Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Aerie Walton, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Natalia Trojacki

Witness Julie Simon

SIGNED and SEALED in the presence of:

Witness Titus Simons III

Witness Ricky Casas

Countersigned by:

Nevada Resident Agent
Non-Resident

Christopher P. Troha

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-553702

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, *up to the amount of* Unlimited :
Derek J. Elston, Christopher P. Troha, Marcia K. Cesafsky, Rachel Fore, Jennifer L. Jakaitis, Bartlomiej Siepierski, Aerie Walton of CHICAGO, Illinois

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of November 15, 2022

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Renaissance Lakewood, LLC — MDEG License # (if applicable): WH02198

Physical Address: 1200 Paco Way

City: Lakewood — State: NJ — Zip: 08701

Mailing Address (if different from physical address): 1200 Paco Way

City: Lakewood — State: New Jersey — Zip: 08701

Telephone: (732) 367-9000 — Website: www.renpharm.com

Licensing Company Email: julie.simon@renpharm.com

Section 2: Personal Information

First: Jeffrey — Middle: Frank — Last: Higginson

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X

Mailing Address: 1200 Paco Way

City: Lakewood — State: New — Zip: 08701

Telephone: (732) 367-9000 — Email: julie.simon@renpharm.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
York University		01/97 - 12/00	
Address	**City**	**State**	**Zip**
4700 Keele Street	Toronto	ON	M3J 1P3
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
The University of Western Ontario		09/92-04/96	
Address	**City**	**State**	**Zip**
1151 Richmond Street	London	ON	N6A 3K7
Diploma/Degree obtained, if any			
Bachelor of Engineering			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/06/2022 Current	[redacted]	Point Pleasant Beach	NJ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
08/15/202 04/06/202		Hawthorn Woods	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Renaissance Lakewood, LLC			12/21-Present	
Business Address		**City**	**State**	**Zip**
1200 Paco Way		Lakewood	NJ	08701
Phone	**Title**		**Number of Employed Hours**	
(732) 367-9000	VP Operations		40 hours per	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Takeda			08/21-12/21	
Business Address		**City**	**State**	**Zip**
1200 Lakeside Dr		Bannockburn	IL	60015
Phone	**Title**		**Number of Employed Hours**	
(224) 554-6500	Site Head		40 hours per	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Baxter Healthcare			1996-2021	
Business Address		**City**	**State**	**Zip**
1 Baxter Pkwy		Deerfield	IL	60015
Phone	**Title**		**Number of Employed Hours**	
(224) 948-2000	Senior Director/Director, Engineering		40 hours per	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07 Nov 2025
Date

I, Jeffrey Higginson, **certify that as the MDEG Administrator for**

Renaissance Lakewood, LLC,

that I (initial that you have read and meet the following requirements):

1. JH Have a high school diploma or its equivalent;
2. JH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Higginson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07 Nov 2025
Date

Board Use Only	Date Received: 12/3/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Renaissance Lakewood, LLC

Pharmacy/Wholesaler License # (if applicable) WH02198

Physical Address 1200 Paco Way

City Lakewood State NJ Zip 08701

Mailing Address (if different from physical address)

City 1200 Paco Way State New Jersey Zip 08701

Telephone (732) 367-9000 Website www.renpharm.com

Licensing Company Email julie.simon@renpharm.com

Section 2: Personal Information

First Jeffrey Middle Frank Last Higginson

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 1200 Paco Way

City Lakewood State New Jersey Zip 08701

Telephone [redacted] Email Jeffrey.Higginson@renpharm.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
York University		01/97-12/2000	
Address	City	State	Zip
4700 Keele Street	Toronto	Ontario	M3J 1P3
Diploma/Degree obtained, if any			
MBA			
School Name		From - To (MM/YY – MM/YY)	
The University of Western Ontario		09/92-04/96	
Address	City	State	Zip
1151 Richmond St	London	ON	N6A 3K7
Diploma/Degree obtained, if any			
Bachelor of Engineering			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/22 to Present	[redacted]	Point Pleasant Beach	NJ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
08/17 - 4/22		Hawthorn Woods	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Renaissance Lakewood, LLC			12/21-Present
Business Address	**City**	**State**	**Zip**
1200 Paco Way	Lakewood	NJ	08701
Phone	**Title**	**Number of Employed Hours**	
(732) 367-9000	VP Operations	40 hours per week	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Takeda			08/21-12/21
Business Address	**City**	**State**	**Zip**
25212 IL Rte 1200	Bannockburn	IL	60073
Phone	**Title**	**Number of Employed Hours**	
(224) 554-6500	Site Head	40 hours per	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Baxter Healthcare			1996-2021
Business Address	**City**	**State**	**Zip**
25212 W IL Rte 120	Round Lake	IL	60073
Phone	**Title**	**Number of Employed Hours**	
(224) 948-2000	Senior Director / Director, Engineering	40 hours per week	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Jeffrey Higginson, **certify that as the designated representative for**

Renaissance Lakewood, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JH I am at least 21 years of age;
3. JH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeffrey Higginson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07 Nov 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Higginson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07 Nov 2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Ocean

I, Jeffrey Higginson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07 Nov 2025

Date

Subscribed and Sworn to before me this 7 day of November 2025

Notary Public Signature

MARCIA A CUCCIO
Notary Public, State of New Jersey
Commission Expires May 8, 2028

(Seal)

Employee Name (Last Suffix, First MI)		
Acker, Robert		
Agnello, Giacomo		
Alberque, Carleen		
Ali, Rashid		
Allen, Edward D.		
Amaro, Luis A.		
Amatucci, Olivia R.		
Anippah, Adilis		
Arcales, Patrick		
Arena, Ann M.		
Asafu-Adjaye, Nana A.		
Atienza, Kim Patrick		
Atif, Sidra		
Atkins, Christopher		
Atkinson, Alonzo		
Avenido, Maria		
Averion, Lloyd		
Ayala, Felipe		
Bader, Joshua		
Baier, Richard		
Bailey, Tanesha		
Banasiak, Conner		
Banner, Kyle W.		
Barber, Marie A.		
Barber, Robert G.		
Barboza-Quesada, Mia A.		
Barrness, Gary		
Basile, Anthony J.		
Battiato, Lynda		
Belias, Amari		
Bender, Chelsi		
Bender, Ella		
Bennett, Amanda M.		

Bennett, Jennifer		
Berardo, Caitlin J.		
Berecsky, Robert J.		
Bianco Sr., William J.		
Bianco, Joseph		
Bilal, Umyma		
Birchfield III, James H.		
Biskunda, Shivani		
Bisozio, Christopher		
Boakye, Richard		
Boito, Matthew		
Bossa, Jesse		
Botsakos, Matthew		
Bowen, Nicole		
Bradley, Dylan M.		
Brautigan, Margaret		
Brennan, Daniel		
Brill, Meagan		
Broussard, Arnold		
Brown, Sherri		
Buczynski, Paul		
Budi, Tracey		
Buonocore, Dante		
Burns, Terry M.		
Byers, Lori		
Calderon, Katherine		
Campbell, Myrna L.		
Cano, Maria J.		
CARABALLO, REYDA B.		
Carannante, Anthony		
Cartelli, Cecelia		
Cassidy, Kevin F.		
Castro, Osvaldo		
Catarata, Daniel		

Cavallaro, Christina		
Chacon, Amarilys		
Chan, Gary		
Charles, Dares		
Chau, Melissa		
Chavan, Yash N.		
Chitongo, Anesu S.		
Chowdhury, Chisty		
Chowdhury, Ishmam		
Christy, Michael J.		
Cloyes, Ryan		
Colianni, Heather		
Collins, Kevin		
Colon, Mildred		
Colvin, Robin C.		
Cosolaro, Stephen		
Costello, Brian		
Coto Flores, Rosa		
Cotter, Thomas J.		
Cowan, Evan		
Cranmer, Blake A.		
Cruz, Angel L.		
Cruz, Daniel M.		
Cuccio, Marci		
Cuppari, Anthony		
Curry, Constance		
Cushing, Christopher		
Custodio Alcantara, Lynet		
Dabrowiecki, Angela L.		
David, Patricia		
Davis, Elisabeth		
Davis, Eric		
De Leon, JJ R.		
Deaver Jr., Jack D.		

Decape, Jeany		
Del carpio alva, Roberto M.		
Del Mundo, Chester		
Delaney, Lauren		
Delgado, Gina		
Dellanno, Karla		
Demian, Brienna		
DeSanctis, Grace		
Dexter, Carlene		
DHARIA, HERSH		
Di Gennaro, Nicholas		
Diaz, Cruz M.		
D'Oleo, Jossip		
Doster Sr., Donnell S.		
Dragone, Diane		
Dunleavy, Alexander R.		
Duran, Carmen		
Dwekat, Faris		
Eak, Kevin J.		
Ebeling, Julia L.		
Ellie, Christiana		
English, Brian		
Ernst, Kimberly		
Ernst, Thomas		
Esposito, Zachary A.		
Ewan, Michael		
Fernandez Perez, Edgar		
Fernandez Perez, Sergio		
Ferrell Sr., Calvin		
Fink, Theodore		
Fischer, Ashlyn		
Fischer, Shannon		
Flanagan, Michael T.		
Fleurant, Donald		

Fornino, Lisa		
Foy, Thomas P.		
Gadson, Darryl B.		
Galvan II, Juan H.		
Garcia, Adam		
Gates, Andrew		
Gayanilo, Steven		
Gdovin, Brittany		
Genao, Manuel D.		
Getta, Alexis		
Giddens, Neikoya		
Gilmartin, Stefan A.		
Giraldo Calvache, Patricia		
Gleason, Todd J.		
Gold, Sharon		
Goldberg, Kathleen		
Golla, Steven W.		
Gomes, Nelson		
Grams, Thomas		
Greenstein, Craig B.		
Gribbon, James		
Gunn, Evan		
Hajisafari, Kaitlyn		
Hall, Aquil D.		
Hall, Jamillah		
Harmon, Robert		
Harrer, Robert		
Hart, Alfonzo		
Hassa, Ross		
Hay, Tracy		
Heim, Glenn		
Henry, Donna		
Henry, Paul		
Herbert, Robert W.		

Hernandez, Arminda		
Hernandez, Luz		
Higginson, Jeffrey		
Hill, Arguirre		
Hines, Travis C.		
Hinger, Lauren		
Hoven, Glenn		
Hrabinski Jr., Christopher M.		
Hradil, Justin		
Huang, Miao Q.		
Huber, Christopher		
Hubschman, Christopher		
Ignace, Kimberly		
Imbert, Katrina		
Intravartolo, John J.		
Irizarry, Maura E.		
Irons, Elena		
Ismail, Katib H.		
Iyengar, Alaka N.		
Izquierdo, Flor		
January, Cathleen		
Jaramillo, Juan J.		
Jeangilles, Darline		
Jehn, Robert W.		
jimenez, jose		
Johnson, Mark D.		
Johnson, Waka		
Joy, Anu		
Joyner, Lori		
Kaneps, Eric N.		
Kanze, Chelsea L.		
Kardashian, Lindsey M.		
Karl, Peter		
Kaszubski, Michal R.		

Katz, Miguel		
Kaur, Kulwant		
Kavaliauskaite, Migle		
Keane, Nicholas P.		
Keating, Daniel		
Keating, Debra R.		
Kengkat, Salakchit		
Khalil, Haamdi-dahab		
Khokhani, Parul		
Kilimnik, Matthew		
Kim, Haerin		
Knapp, Robert		
Kolacz, Robert		
Krieg, Cassondra		
Kutne, Nicole		
Lago, Jessica		
Lago, Jose		
Lajara, Dennes		
Lamkin, Luke		
Landi, Edward		
Lang, James F.		
Larbalestrier, Esperanza		
Larsen, Laura		
Lawrence, Dana R.		
Lawson, Madison		
Lay, Bonnie		
Layton, Janet		
Lazo, Cristian		
Lehman, Douglas		
Leonard, Shawn		
Levine, Jeffrey		
Lewis, Avery		
Libretti, Christine		
Lippett, Joanne		

Livesey Sr., Patrick		
Lizaso, Josefina		
Longobardi, Erica		
Lopez Peralta, Nydia		
Lopez, Alejandro		
Lopez, Aracely		
Lopez, Mildred M.		
Lotruglio, Jeremy		
Lugo, Adriana		
Lugo, Dorca		
Lugo, Migdalia		
Lunsford, Gregory		
Ly, Sylvia		
Lynch, Michael P.		
Macartney, Alyssa		
MacAvoy, Ryan C.		
Maestri, Gregory		
Magner, Courtney		
Mahon, Patrick		
Maietta, Erin		
Makuch, Maxwell		
Malinowski, Maureen		
Maltais, Serge		
Mandracchia, Matthew		
Manickavasagam, Dharani		
Manzano, Adriana		
Marini, Louise		
Marino, Michael		
Marku, Ndrit		
Marrero, Wilfredo		
Marrone, Amanda T.		
Marshall, Rodney		
Martinez, Ana M.		
Maya, Justin		

Mazza, Heather		
Mcaleavy, Jonathon		
McCabe, Jenna E.		
McConnell, Delaney J.		
McKinney, Erika		
Mcneil, Robert		
Mcreynolds, Lilly V.		
Meachem, Brianna		
Medina, Stella		
Melendez, Ivonne		
Memon, Bahzad		
Mercadante, Michael		
Mercedes, Ascencion		
Merkel, Felicia		
Merlucci, Ralph		
Mershon, Melissa N.		
Metro, Richard		
Meyer, Christopher		
Meyer, John		
Micolucci, Nicola		
Miller, Angeline		
Milliken, Kelsey		
Mohamed Ali, Ammar		
Montes, Omar		
Montilla, Jesus		
Mora-Gil, Jose F.		
Moran, Kymberly		
Morris, Sherry		
Morris, Valerie		
Morton III, John		
Mulik, Rohit		
Mulvey, Matthew T.		
Murphy, Dennis		
Murphy, Douglas F.		

Narh, Sheila		
Nash, Eris S.		
Nelson, Brent		
Neris, Maritza		
Nilson, Eric		
Nivar, Andrew G.		
Noguera, Luis A.		
Nolte, Theresa		
O'Brien, Devin		
O'brien, Jessica		
Ojo, Olutoyin		
O'Keefe, Daniel		
O'Neill, Kenn		
O'Reilly, Brian		
Orlasky, Anthony		
Papierman, Keith D.		
Parker, Bryan P.		
Parliament, Betty A.		
Parra, Diana		
Patel, Ashishkumar S.		
Patel, Bhumini		
Patel, Herini		
Patel, Janki		
Patel, Jay		
Patel, Kashmira		
Patel, Paresh		
Patel, Parul D.		
Patel, Pragna B.		
Patel, Rajvi		
Patel, Sheetal		
Patel, Tanmay M.		
Patel, Tripti A.		
Patterson, Sean		
Perez, Christine		

Perez, Israel		
Perez, Maria		
Perez, Michael		
Perry Jr., Earl W.		
Petercsak, Kris		
Pfeifer, Kimberly		
Pharis, Ashleigh M.		
Pharis, Elizabeth		
Pharis, Regina		
Pilovsky Jr., Thomas		
Pineda, Zoyla I.		
Pino, Eric		
Pinon, Rizalyn		
Platt, Craig		
Plungis, Randy		
Poccia IV, John		
Porcello, Nicole		
Powell, Mary		
Preston, Latanya		
Price, Donette		
Promisel, Brad		
Pronovost, Kayla M.		
Quiles, Erika		
Quinn, Nicole		
Quinones, Elliot A.		
Quinones, Joann M.		
Radford, Charlotte		
Raffone, Renee		
Ramirez, Oscar		
Ransom, Derek J.		
Ransom, Esther		
Rasczyk, Richard		
Rawlins, Avrill		
Reshamwala, Shreeda		

Riccobono, Paul J.		
Rich, Joseph		
Richards, Terrance		
Richiuso, Anthony		
Richiuso, Daniel		
Rios, Joseph		
Rivera Ramirez, Angel A.		
Rodriguez, Daniel		
Rojas, Maria F.		
Romano, Roseann		
Romans, Jennifer		
Romero, Melisa		
Romulus, Rudy		
Rowe, Latoya		
Rubin, Darlene		
Rubio, Myrna L.		
Salas, Rachel		
Sales, Jan N.		
Sanchez, Kevin G.		
Sandoval, Ana		
Sangamnerkar, Swagat		
Sathyanarayana, Leela		
Savoth, Alexis		
Scapati, Dayna		
Schmidt, June		
Schneidt, Danielle		
Schneller, Brian		
Schnurpfeil, Curtis A.		
Scott, Vickey		
Semna, Ahmer		
Sepulveda, Robert		
Shah, Shrey A.		
Shah, Tapaskumar		
Shannon, Cyerra		

Shirley, Lauren		
Showanes, Brittany		
Shukla, Pankil T.		
Shukla, Tarakkumar J.		
Sikaloska, Serife		
Simms, Denise		
Simon, Julie M.		
Skiff, Susan C.		
Skillman, Diane		
Sliwinski, Paul		
Smith, Ian		
Smith, Norman		
Sochaski, Michael		
Sommer, William E.		
Soriano, Guadalupe		
Sovine, Aneta A.		
Spadaccino, Mindy L.		
Spadola, Matthew		
Squires, Daniella J.		
Srinivasan, Divya		
Stapleton, Jarrett M.		
Steigerwalt, Devon		
Steward, Jeffrey A.		
Stinvil I, Naylie		
Stout, Jerome		
Street, Marvin		
Strickland, Donna K.		
Suity, Malgorzata		
Sunico, Arlene C.		
Suthar, Archana		
Swasey, Stephanie		
Sweador, Jeffry D.		
Sytko, Michael P.		
Szemiot, Doriann		

Szezypta, Maria C.		
Tenner, Alexander		
Tereman, Christopher		
Thaw, Andrew		
Thum, Thomas		
To, Lynn		
Tomasino, Andrew		
Tonks, Cindy M.		
Torres, Isaiah		
Torres, Matthew		
Trojacki, Natalia		
Turner, My P.		
Unger, Carl		
Valencerina, Guillermo P.		
Valencia, Francisco		
Valentino, Jacqueline		
Valerino, Carlos D.		
Vanostenbridge I, Jeffrey C.		
Velasquez, Elbia		
Ventrice, Nicholas F.		
Vodrazka Jr., Emil		
Vohrer, Danielle		
Vuono, Michael		
Wachowiak-wojcik, Agata		
Wagner, Andrew F.		
Ward, Christine G.		
Ward, Melissa		
Warner, Justin		
Wells, Bruce C.		
Wengryn, Timothy		
Werntz, Elsa G.		
Wheeler, Edward		
White, William E.		
Whitely, Catherine		

Wilson, Carol		
Wilson, Tonya		
Winters, Helene		
Wiswall, Grant C.		
Wood, Robert E.		
Wood, Robert W.		
Wooten, Linda		
Xiang, Chaorui		
Yates, Joshua		
YELDER III, WILLIAM J.		
Yelner, Amanda		
Yoncak, Richard A.		
Young, Jeffrey R.		
Zafar, Hamad		
Zafar, Salman		
Zhang, Junjia		
Zhao, Dehong G.		

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH03470	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Reliable HealthCare Logistics, LLC

Physical Address: 951 Clint Moore Road

City: Boca Raton State: FL Zip: 33487

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Name of Designated Representative (DR): Lizbeth Hernandes

Licensing Company Email: 951LICENSE@RHCL3PL.COM DR Email: lhernandes@reliablehealthcarelogistics.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	■ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	■ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Surgical Centers		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Trusted Partner Pharma Logistics, LLC

Corporation/Organization Name: Reliable HealthCare Logistics, LLC

Mailing Address: 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 216 Email: 951license@rhcl3pl.com

Contact Person Name: Lizbeth Hernandes

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Reliable HealthCare Logistics, LLC

Facility Name

Benjamin Maizel

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/29/25

Date

Board Use Only	Date Received: 11/4/25	Amount: $1000 EK 012654

An official website of the United States government Here's how you know

FDA

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Drug Establishments Current Registration Site

New Search

Search Results for *Reliable HealthCare Logistics*

Showing 1 to 1 of 1 entries (filtered from 5 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Reliable Healthcare Logistics, LLC	3024580094	118777533	RELABEL; REPACK	951 Clint Moore Rd Ste A, Boca Raton, Florida (FL) 33487-2804, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Monday, Oct 28, 2024

New Search

Verified MJH 11/5/25

Reliable
HealthCare Logistics

Entity Organization Chart



Reliable HealthCare Logistics, LLC

List of Officers

Full Name: Benjamin Ephraim Maizel, as sole manager of Reliable HealthCare Logistics, LLC

Title: Chief Executive Officer

DOB: [redacted]

Home Address: [redacted]

Business Address: 951 Clint Moore Road, Suite A, Boca Raton, FL 33487

Email Address: bmaizel@rhcl3pl.com

Phone Number: [redacted]

Reliable HealthCare Logistics, LLC

Reliable HealthCare Logistics, LLC provides Third Party Logistics (3PL) services specializing in supply chain solutions for the healthcare industry. Reliable HealthCare Logistics, LLC occupies a 77,760 square food industrial facility in Boca Raton, FL.

Reliable HealthCare Logistics, LLC is maintained with a Controlled Room Temperature (CRT) of 68° F - 77°F and a secure environment that is properly license to meet FDA requirements.

Reliable HealthCare Logistics, LLC performs specific warehouse functions for receiving, storage, inventory management, order processing, fulfilment, transportation, and reporting. Reliable HealthCare Logistics, LLC stores and distributes Rx, Dietary supplements, Medical Device, and cosmetics.

Our Alarm System is with Johnson Controls Security Solutions which includes Burglar Alarm System, Access, Cards, and Video

Our Business Hours are 8:30 A.M. – 5:00 P.M. Monday – Friday.

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RELIABLE HEALTHCARE LOGISTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF AUGUST, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RELIABLE HEALTHCARE LOGISTICS, LLC" WAS FORMED ON THE FOURTH DAY OF MARCH, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6655021 8300

SR# 20252605244

Authentication: 203771864

Date: 08-23-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

CERTIFICATE OF FORMATION
OF
RELIABLE HEALTHCARE LOGISTICS, LLC

This Certificate of Formation of Reliable HealthCare Logistics, LLC is to be filed with the Secretary of State of the State of Delaware pursuant to Section 18-201 of the Delaware Limited Liability Company Act.

1. The name of the limited liability company is Reliable HealthCare Logistics, LLC.

2. The address of the limited liability company's registered office in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of the limited liability company's registered agent at such address shall be National Registered Agents, Inc.

Dated as of this 4th day of March, 2022.

/s/Rebecca Ware
Rebecca Ware, Authorized Person

32593134.1

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:35 PM 03/04/2022
FILED 01:35 PM 03/04/2022
SR 20220886439 - File Number 6655021

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Third Party Logistics Provider HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

RELIABLE HEALTHCARE LOGISTICS LLC

951 CLINT MOORE ROAD, SUITE A
BOCA RATON FL 33487

LICENSE NUMBER: 02523

EXPIRATION DATE: DECEMBER 31, 2027

Always verify licenses online at MyFloridaLicense.com

ISSUED: 12/01/2025

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

KINSALE INSURANCE COMPANY
2035 Maywill Street, Suite 100
Richmond, VA 23230

DECLARATIONS - LIFE SCIENCES GENERAL LIABILITY - CLAIMS MADE

Policy Number:	0100210519-3
Producer Number:	10014
Name and Address:	RSG Specialty, LLC - Jupiter, FL (AR) 150 S. US Highway 1, 3rd Floor Jupiter, FL 33477

NAMED INSURED:	Reliable Healthcare Logistics LLC
MAILING ADDRESS:	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
POLICY PERIOD:	FROM 10/11/2025 TO 05/12/2026 at 12:01 AM at the address of the named insured as shown above.

IN RETURN FOR THE PAYMENT OF THE PREMIUM, AND SUBJECT TO ALL THE TERMS OF THIS POLICY, WE AGREE WITH YOU TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

LIMITS OF INSURANCE		
Each Claim Limit	$1,000,000	Any one occurrence
Damage to Premises Rented to You Limit	$50,000	Any one premises
Personal and Advertising Injury Limit	$1,000,000	Any one person or organization
General Aggregate Limit	$2,000,000	
Products-Completed Operations Aggregate Limit	$2,000,000	

DEDUCTIBLE(S)	
Each Claim Deductible	$15,000

RETROACTIVE DATE

THIS INSURANCE DOES NOT APPLY TO "BODILY INJURY", "PROPERTY DAMAGE" OR "PERSONAL AND ADVERTISING INJURY" WHICH OCCURS BEFORE THE RETROACTIVE DATE, SHOWN BELOW.		
RETROACTIVE DATE (General Liability):	10/11/2022	at 12:01AM at the address of the named insured as shown above.

DESCRIPTION OF BUSINESS	
DESCRIPTION OF OPERATIONS:	**Pharmaceutical Distributor, Repackager, Relabeler**
BUSINESS TYPE:	Limited Liability Co

ALL PREMISES YOU OWN, RENT OR OCCUPY (If different than the mailing address)	
LOCATION	ADDRESS OF ALL PREMISES YOU OWN, RENT OR OCCUPY
1	1113 Gillingham Lane, Suite A, Sugar Land, TX 77478
2	751 NW 33rd St, Suite 190, Pompano Beach, FL 33064
3	5653 Creekside Pkwy, Lockbourne, OH 43137
4	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
5	6 Wheeling Rd, Dayton, NJ 08810

CLASSIFICATION AND PREMIUM					
CLASS CODE	CLASS DESCRIPTION	BASIS OF PREMIUM	EXPOSURE	RATE	PREMIUM
52343.02.21	Drug, Medicine or Pharmaceutical Preparations Mfg. - other than for animal use	per $1,000 Gross Sales	8,753,425	3.12	$27,298

TOTAL PREMIUM (DEPOSIT PREMIUM):	$27,298
COMPANY FEE:	$300
TOTAL PAYABLE AT INCEPTION:	**$27,598**

POLICY SUBJECT TO AUDIT:	Y	AUDIT PERIOD:	Annual

FORMS AND ENDORSEMENTS
Refer to ADF4001, SCHEDULE OF FORMS

THESE DECLARATIONS, TOGETHER WITH THE COMMON POLICY CONDITIONS AND COVERAGE FORM(S) AND ANY ENDORSEMENT(S), COMPLETE THE ABOVE NUMBERED POLICY.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11499812250

Application/License No. _____

RELIABLE HEALTHCARE LOGISTICS, LLC, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
951 CLINT MOORE ROAD, SUITE A, BOCA RATON, FL, 33487, as
Address of Applicant/Principal
PRINCIPAL, and Philadelphia Indemnity Insurance Company, a
Surety Company
corporation organized under the laws of the state of Pennsylvania
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Bala Plaza, Suite 100 BALA CYNWYD PA 19004 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Aug 30, 2025.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of September, 20 25.

APPLICANT/PRINCIPAL
RELIABLE HEALTHCARE LOGISTICS, LLC
COMPANY

Authorized Representative

SURETY
Philadelphia Indemnity Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

PHILADELPHIA INDEMNITY INSURANCE COMPANY * CORPORATE SEAL 1927 PENNSYLVANIA

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed $50,000,000.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**, that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1386394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 15th day of September, 2025.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

To verify the bond please visit https://www.suretybond.org/validate/?code=fVhD1U1Q4EaXhXA15TXkVADg&transaction=XFkG0VQV16owheQwh1266CQ

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
Mortgage loans	980,210	1,060,940
Real estate	45,943	21,033
Derivatives	3,552	-
Other invested assets (cost $219,302 and $201,673)	229,008	226,716
Receivables for securities sold	329	4,072
Cash, cash equivalents and short-term investments	176,533	147,539
Cash and invested assets	11,237,195	10,754,075
Premiums receivable, agents' balances and other receivables	1,166,132	1,108,771
Reinsurance recoverable on paid loss and loss adjustment expenses	63,067	57,589
Accrued investment income	94,377	93,350
Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 6,059,913	$ 5,797,285
Unearned premiums	1,990,597	1,887,004
Reinsurance payable on paid loss and loss adjustment expenses	39,877	35,204
Federal income taxes payable	-	2,352
Ceded reinsurance premiums payable	183,308	152,393
Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
Accrued expenses and other liabilities	54,505	62,438
Total liabilities	8,815,290	8,365,456
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Reliable HealthCare Logistics, LLC — MDEG License # (if applicable): WH03470

Physical Address: 951 Clint Moore Road

City: Boca Raton — State: FL — Zip: 33487

Mailing Address (if different from physical address):

City: — State: — Zip:

Telephone: 561-998-3885 Ext 216 — Website: www.reliablehealthcarelogistics.com

Licensing Company Email: 951LICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Lizbeth — Middle: Stephanie — Last: Hernandes

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: 951 Clint Moore Road, Suite A

City: Boca Raton — State: FL — Zip: 33487

Telephone: 561-998-3885 Ext 216 — Email: lhernandes@reliablehealthcarelogistics.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern University		05-2016	
Address	**City**	**State**	**Zip**
3300 S University Dr	Fort Lauderdale	FL	33328
Diploma/Degree obtained, if any			
Bachelor of Science in Paralegal Studies			

School Name		From - To (MM/YY – MM/YY)	
Palm Beach State College		2011- June 2012	
Address	**City**	**State**	**Zip**
4200 S Congress Ave	Lake Worth Beach	FL	33461
Diploma/Degree obtained, if any			
Associate of Applied Science in Paralegal Studies			

School Name		From - To (MM/YY – MM/YY)	
Trust School in Tampa		July 2008	
Address	**City**	**State**	**Zip**
100 2nd Avenue South, Suite 1204-S	St. Petersburg	FL	33701
Diploma/Degree obtained, if any			
First year of Trust School in Tampa			

School Name		From - To (MM/YY – MM/YY)	
East Hartford High School		1997-2001	
Address	**City**	**State**	**Zip**
869 Forbes St	East Hartford	CT	06118
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2007 - Present	[redacted]	Delray Beach	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/2022 - Present	
Business Address		**City**	**State**	**Zip**
951 Clint Moore Road, Suite A		Boca Raton	FL	33487
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 216	Regulatory License Specialist		9,208	
Description of Duties				
Regulatory/Licensing Specialist Ensure all 3PL facilities quality of professional service is maintained and that the licensing remains in compliance with State, NABP, and Federal laws.				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			03/2018 - 08/2022	
Business Address		**City**	**State**	**Zip**
951 Clint Moore Road, Suite A		Boca Raton	FL	33487
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 216	Accounting Manager/Compliance Specialist		6,248	
Description of Duties				
Responsible for maintaining all elements of the Accounting Department. Ensure all 3PL facilities quality of professional service is maintained and that the licensing remains in compliance with State, NABP, and Federal laws.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/industry/Entity				

Provide explanation below:

Hfernandes
Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

I, Lizbeth Hernandes, **certify that as the MDEG Administrator for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements):

1. LH Have a high school diploma or its equivalent;
2. LH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. LH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. LH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lizbeth Hernandes
Print Name (First, Last)

Hernandes
Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

Board Use Only	Date Received: 11/4/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Reliable HealthCare Logistics, LLC

Pharmacy/Wholesaler License # (if applicable): WH03470

Physical Address: 951 Clint Moore Road

City: Boca Raton State: FL Zip: 33487

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 561-998-3885 Ext 216 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: 951LICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Lizbeth Middle: Stephanie Last: Hernandes

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 216 Email: lhernandes@reliablehealthcarelogistics.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern University		05-2016	
Address	**City**	**State**	**Zip**
3300 S University Dr	Fort Lauderdale	FL	33328
Diploma/Degree obtained, if any			
Bachelor of Science in Paralegal Studies			

School Name		From - To (MM/YY – MM/YY)	
Palm Beach State College		2011- June 2012	
Address	**City**	**State**	**Zip**
4200 S Congress Ave	Lake Worth Beach	FL	33461
Diploma/Degree obtained, if any			
Associate of Applied Science in Paralegal Studies			

School Name		From - To (MM/YY – MM/YY)	
Trust School in Tampa		July 2008	
Address	**City**	**State**	**Zip**
100 2nd Avenue South, Suite 1204-S	St. Petersburg	FL	33701
Diploma/Degree obtained, if any			
First year of Trust School in Tampa			

School Name		From - To (MM/YY – MM/YY)	
East Hartford High School		1997-2001	
Address	**City**	**State**	**Zip**
869 Forbes St	East Hartford	CT	06118
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2007 - Present	[redacted]	Delray Beach	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/2022 - Present	
Business Address		**City**	**State**	**Zip**
951 Clint Moore Road, Suite A		Boca Raton	FL	33487
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 216	Regulatory License Specialist		9,208	
Description of Duties				
Regulatory/Licensing Specialist Ensure all 3PL facilities quality of professional service is maintained and that the licensing remains in compliance with State, NABP, and Federal laws.				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			03/2018 - 08/2022	
Business Address		**City**	**State**	**Zip**
951 Clint Moore Road, Suite A		Boca Raton	FL	33487
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 216	Accounting Manager/Compliance Specialist		6,248	
Description of Duties				
Responsible for maintaining all elements of the Accounting Department. Ensure all 3PL facilities quality of professional service is maintained and that the licensing remains in compliance with State, NABP, and Federal laws.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

I, Lizbeth Hernandes, **certify that as the designated representative for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LH I am at least 21 years of age;
3. LH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lizbeth Hernandes

Print Name (First, Last)

Hernandes

Original Signature (electronic, copies or stamps not accepted)

10/29/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lizbeth Hernandes

Print Name (First, Last)

Hernandes.

Original Signature (electronic, copies or stamps not accepted)

10/29/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, Lizbeth Hernandes., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Hernandes.

Original Signature

10/29/2025

Date

Subscribed and Sworn to before me this 29th day of October.

Robert Gerstein

Notary Public Signature

Notary Public State of Florida
Robert Gerstein
My Commission HH 317403
Expires 9/28/2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Reliable HealthCare Logistics, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03470

Physical Address: 951 Clint Moore Road

City: Boca Raton State: FL Zip: 33487

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: 951LICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Benjamin Middle: Ephraim Last: Maizel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dunedin State: FL Zip: [redacted]

Telephone: [redacted] Email: bmaizel@rhcl3pl.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fairleigh Dickenson University		1980-1983	
Address	**City**	**State**	**Zip**
1000 River Rd	Teaneck	NJ	07666
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Florida Gainesville		9/1975 - 6/1979	
Address	**City**	**State**	**Zip**
1478 Union Rd	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018 - Present	[redacted]	Dunedin	FL	[redacted]
2007-2018		Palm Harbor	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/01/2025 - Present	
Business Address	**City**	**State**	**Zip**	
951 Clint Moore Road, Suite A	Boca Raton	FL	33487	
Phone	**Title**			
561-998-3885 Ext 207	CEO			
Description of Duties				
CEO of Third-Party Logistics company, focused on the healthcare industry, specifically Generic Pharmaceutical companies.				

Business Name			From - To (MM/YY – MM/YY)	
Trusted Partner Pharma Logistics			01/2023 - Present	
Business Address	**City**	**State**	**Zip**	
3783 Winning Stakes Way	Mason	OH	45040	
Phone	**Title**			
716-553-9641	CEO & Co-Founder			
Description of Duties				
CEO & Co-Founder, Formed specific company to launch a generic focused 3PL				

Business Name			From - To (MM/YY – MM/YY)	
DiRx Inc			03/21 - 07/23	
Business Address	**City**	**State**	**Zip**	
2 TOWER CENTER Blvd Floor 12	East Brunswick	NJ	08816	
Phone	**Title**			
(908) 356-0764	COO			
Description of Duties				
Responsible for all aspects of physical pharmacy, product acquisition, pharmacy team including Customer Service, Outreach and Fulfillment teams, and Compliance.				

Business Name			From - To (MM/YY – MM/YY)	
McKesson Drug			01/2018-03/2020	
Business Address	**City**	**State**	**Zip**	
3600 Pharma Way	Mason	OH	45036	
Phone	**Title**			
866-4479758	Vice President			
Description of Duties				
Completed Operational, Financial, Customer Service transition to RxCrossroads				

Business Name			From - To (MM/YY – MM/YY)	
RXTPL LLC			01/2012 - 12/2017	
Business Address	**City**	**State**	**Zip**	
3600 Pharma Way	Mason	OH	45036	
Phone	**Title**			
866-447-9758	President			
Description of Duties				
CREATED a 3rd Party Logistics company for pharmaceutical manufacturers. Oversaw all aspects of the company, growing from zero to over 50 international manufacturers and growing business year over year				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Maizel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach.

I, Benjamin Maizel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/29/2025.

Date

Subscribed and Sworn to before me this 29th day of October, 2025.

Notary Public Signature

NOTARY PUBLIC STATE OF FLORIDA

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

(Seal)

Employee list for our 951 Clint Moore Road, Suite A, Boca Raton, FL 33487

Ambroise, Carl	Boca Raton, Florida
Blodgett, Troy M	Boca Raton, Florida
Briceno, Angela C	Boca Raton, Florida
Cook, Jamarcus	Boca Raton, Florida
Correa, Viviana M	Boca Raton, Florida
Faulkner, Jeffrey M	Boca Raton, Florida
Ferreira, Manuella	Boca Raton, Florida
Gerstein, Robert	Boca Raton, Florida
Gomez, Carlos A	Boca Raton, Florida
Hernandes, Lizbeth	Boca Raton, Florida
Hernandez Ochoa, Mariana J	Boca Raton, Florida
Hincapie, Doris S	Boca Raton, Florida
Iamunno, Dina	Boca Raton, Florida
Jocelin, Andre	Boca Raton, Florida
Johnson, Marisa	Boca Raton, Florida
Joseph, Sandra	Boca Raton, Florida
Laman, Frantz	Boca Raton, Florida
Macias Zavala, Claudia R	Boca Raton, Florida
Maizel, Benjamin E	Boca Raton, Florida
Meza, Julio F	Boca Raton, Florida
Nau, Andre	Boca Raton, Florida
Oleski, Cheryl A	Boca Raton, Florida
Paez Hernandez, Mariu	Boca Raton, Florida
Petit, Wilna	Boca Raton, Florida
Prieto Puentes, Blanca L	Boca Raton, Florida
Sanchez, Gabriela	Boca Raton, Florida
Shipley, Matthew H	Boca Raton, Florida
Sinisgalli, Krysta L	Boca Raton, Florida
Thompson, John	Boca Raton, Florida

Florida dbpr

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
(850) 717-1800
www.myfloridalicense.com

ENTRY NOTICE AND ON-SITE INSPECTION REPORT

DBA Name:		Form Date:	Apr 01, 2025 08:44 - Apr 01, 2025 11:43
Full Legal Name:	RELIABLE HEALTHCARE LOGISTICS LLC	Permit Number:	410 Rank: 02
Inspection Reason:	Routine - P	Telephone Number:	561-998-3885
Address:	951 CLINT MOORE ROAD SUITE A BOCA RATON FL 33487	Inspection Visit ID:	10791971
		File Number:	546
		Permit Type:	3302

INSPECTION RESULT Completed

Inspection Authority 499.051 F.S., 61N-1.019, F.A.C. (03/10/2017)

Person Receiving Report/Title Cheryl Oleski, Quality Assurance Director

Facility Hours 61N-1.015(2)(c), F.A.C.

Hours	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	Closed	Closed
Close	5:00pm	5:00pm	5:00pm	5:00pm	5:00pm	Closed	Closed

FACILITY/STORAGE [(Rx drug establishments) FS 499.01(2) and 499.0121(1)(b),(d),(e)]

1. Is the establishment a residence? [F.S. 499.012(1)(b)]	No	
2. Lighting adequate? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.44] [(Cosmetic manufacturers) 61N-1.010(2)(e), F.A.C.]	Yes	
3. Pest Free? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.56] [(Cosmetic manufacturers) 61N-1.010(2)(b), F.A.C.]	Yes	Inspector as provided invoice/contract
4. Clean and orderly? [(OTC drug manufacturers) 61N-1.014(4), F.A.C.] [(Cosmetic manufacturers) 61N-1.010(2)(a), F.A.C.]	Yes	

RECORD KEEPING [F.S. 499.0121(6)] [61N-1.012 F.A.C.]

5. All records computer based?	No	Mostly electronic, some manual
6. Location of hard copy?		On-site
7. All records manual?	No	Mostly electronic, some manual
8. On-site storage?	Yes	
9. Shares facility?	No	Per Hernandes, Firm does not share facility with another business.
10. If yes to #9, separate records?	N/E	

PRESCRIPTION DRUG ESTABLISHMENT

11. Is the name identical to another person authorized to purchase legend drugs? [F.S. 499.012(1)(c)] [61N-1.015(2)(b), F.A.C.]	No	
12. Is the person a broker only as defined under [61N-1.001(2)(d), F.A.C.]?	No	

SECURITY [(Rx drug establishments) FS 499.0121(2)(a), (b) and 499.0121(10)(b) or 61N-1.013(1), F.A.C.]

13. Access restricted? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.28(c)] [(Cosmetic manufacturers) 61N-1.010(4)(f), F.A.C.]	Yes	
14. Drug facility alarmed?	Yes	Inspector was provided with contract.

Florida dbpr

2601 Blair Stone Road
Tallahassee, Florida 32399-1047
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15. Telephone monitoring?	Yes	
16. Controlled substance cage (CIII-CV)? [21 CFR 1301.72]	N/E	Firm does not have a DEA Lic./no controls
17. Controlled Substance CII vault? [21 CFR 1301.72]	N/E	Firm does not have a DEA Lic./no controls

STORAGE [(Rx drug establishments) FS 499.0121(3)(5) or 61N-1.013(3)(4), F.A.C.] [(OTC drug manufacturers) 61N-1.014, F.A.C., and/or FS 499.01(2)(n)3 and 21 CFR 211.46] [(Cosmetic manufacturers) 61N-1.010(2), F.A.C.]

18. Quarantine area?	Yes	Picture on file.
19. Air conditioner?	Yes	Data logger charts provided to inspector.
20. Method of monitoring?		Data loggers in various locations.
21. Refrigeration present?	Yes	Data logger charts provided to inspector.
22. Handles drugs or cosmetics requiring refrigeration?		
23. Method of monitoring refrigeration?		Continuous monitoring, data logger (see notes)
24. Freezer present?	No	
25. Handles drugs or cosmetics requiring freezing?	No	
26. Method of monitoring freezing temperatures?		

WRITTEN POLICIES AND PROCEDURES [(Rx drug establishments and OTC manufacturers) FS 499.0121(6)(8)(10), 499.01(2) and/or 21 CFR Part 211] [(Cosmetic manufactures) 61N-1.010, F.A.C.]

27. Exist?	Yes	
28. Rx drug annual examination? [F.S. 499.0121(5)(a)2]	Yes	See notes. Approximately,Last calendar day of year (annually)
29. Drug FIFO inventory?	Yes	Yes, see notes
30. Recalls/emergencies?	Yes	SOP provided.
31. Natural disasters for Rx drug establishments?	Yes	SOP provided.
32. Receipt and distribution business records?	Yes	
33. Transaction Information, History and Statement (T3) for Rx drug products?	Yes	

INBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Purchases and/or Receipts) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]

34. What are firm's all-inclusive inbound business records that it receives from its Rx drug source(s) per firm for this establishment?	Rceiving slip, BOL and COA, ASN

OUTBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Sales or Otherwise) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]

35. What are firm's all-inclusive typical outbound business records (e.g., sales invoice, packing list, etc.) that it provides to the purchaser and recipient for each Rx drug distribution from this establishment according to firm?		Packing slip and BOL.
36a. Did firm provide its all-inclusive outbound business records for one (1) of its typical Rx drug distribution?	Yes	Packing slip and BOL
36b. If yes to 36a, what is the tracking number (e.g., sales invoice or order number, etc.) and distribution date for this provided distribution document?		684582580287
37. Of the document(s) provided in 36a, which document contains the minimum required recordkeeping business elements according to firm?		Packing slip

38. For the document type referenced in 37 regarding this establishment's outbound Rx drug distributions:

Florida dbpr

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38a. Did firm mark "A" next to the field that lists the seller's name and address?	Yes	
38b. Did firm mark "B" next to the field that lists the seller's Florida permit number?	Yes	
38c. Did firm mark "C" next to the field that lists the shipper's name and address when different from the seller?	Yes	
38d. Did firm mark "D" next to the field that lists the distribution date?	Yes	
38e. Did firm mark "E" next to the field that lists the name, strength, dosage form, quantity, and (when assigned) the National Drug Code (NDC) of the Rx drug?	Yes	
38f. Did firm mark "F" next to the field that lists the financial data?	N/E	3PL
38g. Did firm mark "G" next to the field that lists the purchaser's name, address, and Florida permit number?	Yes	
38h. Did firm mark "H" next to the field that lists the physical recipient's name, address and permit or license number, when the recipient is different from the purchaser?	Yes	

N/E = Not Evaluated

Inspection Notes

Inspection Notes
Reliable Healthcare Logistics LLC
951 Clint Moore Road Suite A
Boca Raton, Florida 33487
561-998-3885
Inspection Visit ID 10791971
Lic Type 3302
Lic Number 02410
File Number 546

This Inspection is a routine inspection at the request of Reliable Healthcare Logistics LLC for a Third Party Logistics (3PL) provider (3302).

Inspector Anthony Raineri entered the facility at 951 Clint Moore Road, Suite A, Boca Raton, Florida on 4/1/2025 at approximately 10:25am. Inspector Raineri was met by Cheryl Oleski, Quality Assurance Director and Lizbeth Hernandes, Licensing Specialist and Marisa Johnson, QA documentation specialist. Inspector provided credentials and Bill of Rights. Upon entering Inspector Raineri was asked to sign in and state the purpose for visit.

For the purpose of this inspection report, Inspector Anthony Raineri will be referred to as the Inspector, Reliable Healthcare Logistics LLC will be referred to as the FIRM, DBPR will be referred to as the Department, Lizbeth Hernandes (Regulatory/Licensing Specialist) will be referred to as Hernandes.

Reliable Healthcare Logistics LLC holds several permits with the Department. Besides holding the 3PL (3302) the Firm also holds an Over the Counter Drug Manufacture License (3321) License number 21878, an Over the Counter Product Registration permit License number OTC2581, a Prescription Drug Repackager License (3328) License number 2893, a Repackager RX Drug Product Registration permit License number RPK2580), a Complimentary Drug Distributor License (3340) License number 40942, and a Restricted RX Drug Reverse Distributor License (3352) license number 5243. This inspection only refers to the 3PL (3302) License the Firm holds with the Department. (Reliable Healthcare Logistics LLC has 4 other locations. Pompano Beach Fl, Lockbourne OH, Sugar Land TX and Dayton NJ).

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Regarding the 3302 Permit (3PL), the Firm understands they may only provide prescription drug warehousing and distribution services on behalf of prescription drug manufacturers and wholesalers who themselves are permitted to engage in the distribution of prescription drugs into or within the State of Florida. The Firm understands that they may not receive prescription drugs from firms not authorized to distribute prescription drugs into Florida. The Inspector referenced for the Firm 499.005(14) F.S. and 499.01(2)(q) F.S. to review.

Firm ownership:

The owners: Reliable Healthcare Logistics Investments, LLC 100% (Investments is owned by the Holdings)
Mike Kattawar 76%
Tyler Kattawar 5%
Mike Kattawar Sr. 5%
David Kattawar 4%
Jerry Kattawar 5%
Greg Rake 5%
The owners of Reliable Healthcare Logistics Investments, LLC also owns Phoenix Assurance and Kpower Global Logistics which are 3PL's and Power Express which is a freight brokerage company.

Firm has approximately 30 full time employees.
Key Employees:
Tyler Kattawar- COO
Cheryl Oleski- Director of Quality
Krysta Sinisgath- Director of Operations
Vivian Correa- Quality Control Inspector
Larry Russell- Chief Financial Officer
Matthew Shipley- Logistics Manager

Firm's hours of operation are Monday – Friday 8:30am – 5:00pm, closed Saturday and Sunday.

Firm is registered with the FDA. The FDA Establishment Identifier is 3024580094 and DUNS number is 118777533 expires 12/31/2025. Hernandes states the FDA has not visited their site in Boca Raton.

DEA – Hernandes states the Firm does not have a DEA registration and that it does not participate in the distribution of controlled substances.

Facility: Hernandes states the Firm does not share the facility with another business. A Layout of the facility was provided which consist of receiving, storage, offices, returns dept., packing rooms, maintenance etc. Hernandes states the Firm occupies suites A and B. Hernandes states the Firm occupies 72,760 sq ft. The Inspector informed the Firm that any change in address must be communicated with the Department. The Inspector also noted on the layout a cage and 2 vaults, but the Firm does not engage in controlled substance storage or distribution according to Hernandes.

Tour: The Inspector was provided with a tour suite A and B of the facility. Mr Shipley, logistics manager, explained the business model from incoming product to outgoing shipment. Specific areas such as quarantine were noted and explained to the Inspector.

Alarm/Security: Facility is alarmed and monitored by Johnson Controls Security Solutions. The system consists of a Burglar Alarm System, Access Security with door contacts, Video surveillance, motion detectors and glass break. The facility is also equipped with a sprinkler system. Security also exists to protect IT with specific user ID and passwords for each employee and 15-minute interval timeouts are in place for user inactivity. Server files are backed up daily by an off-site vendor, i365 in Utah. Employees undergo a background check prior to employment, and they always escort visitors within the facility after the visitors sign upon entering. In case of an alarm breach, the monitoring company first calls the building then the first authorized employee on the call list. It is then decided if the police are to be notified. The Inspector was provided a copy of Johnson Controls contract.

Pest Control: Hernandes provided the Inspector with Pest Control invoices and a contract. The Firm is serviced by Florida Pest Control, Fort Lauderdale, Florida. The service includes all interior spaces and the outside perimeter. Service is monthly and a detailed map was also provided showing where traps are located and what is being targeted.

Temperature/Humidity: The Firm is maintained with a Controlled Room Temperature (CRT) of 68-77 degrees F. The temperature and humidity are monitored through a continuous electron monitoring system. There are many loggers throughout the warehouse. The Inspector was provided several temperature and humidity graphs showing continuous monitoring and min and max alarm levels for temperature and humidity. Regarding refrigeration and freezer storage. The Firm does store refrigerated products at 2-8 degrees Celsius according to Hernandes. A graph showing continuous monitoring of the refrigeration temperature was provided to the Inspector. Currently, the Firm does not store any products that require freezer storage.

Quarantine: Inspector was provided a picture of a large secure cage with shelfing units that the Firm utilizes for quarantine products. The large cage is clearly labeled. The Firm states in their SOP-WH-001 that products will be quarantined if products appear to be suspicious or criminal activity is suspected, or the possibility of a counterfeit product being received. The Firm will report the incident to the appropriate state regulatory agency, FDA and the manufacturer. The products will remain quarantined until further guidance from the FDA and the authorized regulatory agency. Products are also quarantined after receiving an inbound shipment that is suspected to be adulterate, misbranded, counterfeit or contraband. In this case Quality Assurance Management is notified and proceeds with steps outlined in the SOP.

Receipt/Storage/Distribution: The Client notifies the Firm of an incoming shipment. The Firm enters product information in DATEX which is the Firms electronic business management model for warehousing, storage and fulfillment. The Client will provide a COA and ASN. Products are placed in a designated area (quarantined) waiting to be released for distribution by the Client. Products are stored under appropriate temperature and humidity conditions in accordance to product labeling. Then only inventory issued with a COA, MSDA or SDS (if applicable) and/or Certificate of Compliance (if applicable), Product Release and Packing Slip by the customer/manufacturer will be shipped and distributed.

Natural Disasters/Emergencies: Hernandes provided the Inspector with SOP-WH-007 which outlines the procedures for Natural Disasters, Emergencies/Disaster and a Hazardous Material incident. The SOP includes Preparedness and Recovery Plans regarding a particular event. The Quality Assurance Department and Operations Management is mainly responsible to carry out the plan. The IT Department is responsible for securing computers and recovery of data and other technology equipment (hardware and software).

Inbound: Hernandes states that inbound documents consist of Receiving slip and BOL. (The Inspector was sent copies of inbound documents). Inspector noted that also a COA is included with some inbound documents and a ASN.

Outbound: Hernandes states that outbound documents consist of a Packing slip and BOL. The Inspector was sent copies of both and will use these documents for the exit inspection exercise on the Departments tablet.

Records: Firm uses DATEX which is a fully integrated real-time business management system. It provides electronic modules for warehousing, storage and fulfillment as well as operational, financial and accounting information per SOP WH-002. Records are maintained mostly electronically and some manual. Records are kept for ? years ???? and records are kept on-site ????????? according to

DSCSA: SOP-WH-042 states trading partners such as manufactures, packagers and wholesale distributors must provide and capture drug product tracing information. The Inspector was provided documents at the inspection showing T3, T history and T statement.

Inventory: (FIFO) According to SOP-WH-035, an annual inventory count of the entire warehouse takes place on or about the last business day of each year. Also, daily cycle count procedures occur depending on the product picking methodology within the DATEX System. SOP-WH-031 states the Firm utilizes a FIFO/FEFO rule for shipping of products.

Recalls: The Firm is a 3PL, therefore it does not initiate prescription drug recalls. It is the responsibility of the Client to notify the

FDA of a product recall. The Firm monitors the product status in its DATEX System and if the product is updated to "Recalled" in the system the product is immediately removed from dispensing area and put into a designated area for Quarantine. The recalled prescription drug product will then be processed in accordance to the Client's guidelines.

Reverse Distributor/Destruction: Hernandes states the Firm utilizes Daniels Sharpsmart INC. for Destruction and Reverse Distribution. Certificates of Destruction were provided to the Inspector for Daniels Sharpsmart. The Inspector was provided the Florida permits for Daniels Sharpsmart Biomedical Waste for treatment, storage and transportation.

Bus Tax Receipts and 499/61N: The Firm keeps a current version of 499/61N on its desktop. Also, Palm Beach County and Boca Raton Business Tax Receipts are clearly displayed with the Departments permit. Inspector took photographs of licenses.

Export/Samples/Repackage: Hernandes stated that the Firm does export products. She provided several Bill of Lading documents to the Inspector. Also stated was that the Firm has in the past engaged in Prescription Sampling but at this time they do not engage in this activity and currently does not have a customer with drug sample. Lastly, Hernandes states the Firm currently operates as a Prescription Repackager. The Firm has one client, Snap Medical. The Firm provides a kitting service for a Snap Medical Rx Medical Device that has a drug in it. (The Firm basically assembles the kit for Snap Medical).

Due Diligence: It is the responsibility of the Quality Assurance Department to grant final approval of all Vendors, Customers and Carriers. Vendors and Customers are identified for legitimacy and proper licensing with federal and state agencies. If the Firm is unable to authenticate a vendor or customer or if criminal activity is suspected the appropriate Board of Pharmacy is notified within 3 days. If any criminal activity is suspected regarding DSCSA, the FDA will be notified within 24 hours. All Common Carriers are identified for identity, legitimacy and proper licensing to transport prescription drugs. The Firm will verify with the "Secure Transport Solutions" that a product can be maintained, and that identity, strength, quality and purity are not affected.

Firms Carriers: (Hernandes states all are common carriers)
Advanced Messenger
FedEX
USPS
UPS

Customer Carriers: (Customer schedules their own transportation)
Air 7 Sear
CH Robinson
AAA Cooper
DHL
Odyssey ShipRite
Southeastern Freight
Amazon (for nutraceuticals only)
R+L Carrier
Concordia
FedEx Freight
Estes Express
Total Quality Logistics
Kompass

List of Firms Customers:
Clinuvel, Inc. CA. FL#46251
Ivaoes Animal Health FL Fl #457
Medstone Pharma LLC FL FL#20367
Methapharm, Inc. FL FL#4522
Nextsource Biotechnology, LLC FL FL#456
Snap Medical Industries, LLC OH FL#4689

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The inspector stated to the FIRM that the Department must be notified of a change in ownership or a change of address (also if adding an additional suite to the current address). Any changes such as hours of operation, telephone number or closure of business must be reported to the Department. For Firm's reference, review 499.012(4)(a)(c),(6) F.S. and 61N-1.015(2) F.A.C.

F.S. 499.01(2)(p) a 3PL provider permit is required for any person that contracts with a Rx drug wholesale distributor or Rx drug manufacturer to provide warehousing, distribution or other logistics services on behalf of a manufacturer or wholesale distributor but who does not take title to the Rx drug or have responsibility to direct the sale or disposition of the Rx drugs. Each 3PL provider shall comply with the requirements for wholesale distributors under ss 499.0121 (including recordkeeping of business records, and other requirements) and the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act (DQSA) unless exempt.

Firm advised that records/documents cannot be retroactively created and need to be static 61N-1.012(2)(d)(9) F.A.C. and readily available and retrievable 499.0121(6)(e)F.S. 61N-1.001(2)(s) F.A.C contain minimum key elements 499.0121 F.S. maintained for not less than 6 years and kept separate and distinct from other businesses.
The name firm is doing business in should be the same as the permit name.

Note that specific statues and rule citations have been included in this report for firm's convenience and reference but should not be considered as an all-inclusive representation of applicable regulations. Please refer to Chapter 499 Florida Statues and Rule61N-1 Florida Administrative Code. A link to the statues and rules can be found on the division's websitewww.myfloridalicense.com/dpbr/ddc.

Firm understands firm must be available for inspection during business hours. Firm to review 499.051 F.S., 61N-1.015(2)(c) F.A.C. and 61N-1.019 F.A.C

Firm should establish, maintain and adhere to written policies & Procedures. F.S.499.01(2)(g), 499.0121(8). 61N-1.015(4) F.S. Significant discrepancies must be investigated and handled in accordance to regulations. Rule 61N-1.013(6).

Licensee or Owner Signature

Cheryl Oleski
Quality Assurance Director
951 Clint Moore Rd Suite A
Boca Raton, FL 33487
561 9983885 ext 307
Apr 01, 2025 11:40

Inspector Signature

Anthony Raineri
Apr 01, 2025 11:36

April 1, 2025 at 11:43:38 AM EDT
Location,
License #: 02410
Inspector: Anthony Raineri

Reliable HealthCare Logistics, LLC
License List

RHL Facility	State	License Number	License Type	License Issue Date	License Expiration Date
951 Boca	Florida	TEMP509	Temporary - Third Party Logistics Provider Permit	8/29/2025	11/26/2025
951 Boca	Montana	PHA-WDD-LIC-117717	Wholesale Drug Distributor License	2/28/2023	11/30/2025
951 Boca	Alabama	196455	Third Party Logistics Provider	9/8/22023	12/31/2025
951 Boca	Louisiana	11722	Distributor of Legend Drugs or Legend Devices	9/10/2025	12/31/2025
951 Boca	Maine	WH70003420	Pharmaceutical Wholesaler	4/7/2023	12/31/2025
951 Boca	Mississippi	18623/16.3a	Drug Facility - 3rd Party Logistics (Non-Resident)	2/1/2023	12/31/2025
951 Boca	North Carolina	1690	Third Party Logistics	12/12/2022	12/31/2025
951 Boca	New Jersey	5006197	Wholesale	12/21/2022	1/31/2026
951 Boca	Virginia	0242000276	Non-Resident Third Party Logistics Provider	12/4/2023	2/28/2026
951 Boca	Pennsylvania	3000010483	Distributor of Prescription Drugs	3/5/2023	3/31/2026
951 Boca	Wisconin	10038-45	Wholesale Distributor of Prescription Drugs	9/5/2023	5/31/2026
951 Boca	Alaska	201633	Third-Party Logistics Provider	10/26/2022	6/30/2026
951 Boca	Connecticut	CSW.0005174	Wholesaler of Drugs, Cosmetics & Medical Devices	7/1/2023	6/30/2026
951 Boca	Kansas	23-126188	Third Party Logistics Provider	9/12/2025	6/30/2026
951 Boca	Kentucky	TPL00507	Third Party Logistic	8/15/2025	6/30/2026
951 Boca	South Carolina	23423	Non-Resident Third Party Logistics Provider	8/26/2025	6/30/2026
951 Boca	West Virginia	3PL0000500	Third Party Logistics Provider	8/29/2025	6/30/2026
951 Boca	California	NPL1395	Nonresident Third Party Logistics Provider	8/24/2023	8/1/2026
951 Boca	Delaware	A4-0013070	Pharmacy - Wholesale	5/1/2023	9/30/2026
951 Boca	Distric of Columbia	DM250000585	Non-Resident Distributor	9/17/2025	9/30/2026
951 Boca	Indiana	94000334A	Third Party Logistics Provider	9/19/2025	9/30/2026
951 Boca	Oklahoma	88-L-9229	3PL Provider	09/12/02025	9/30/2026
951 Boca	Oregon	DDA-0000632	Drug Distribution Agent	3/13/2023	9/30/2026
951 Boca	Rhode Island	DIS03844	Drug Wholesaler - Out of State	12/20/2022	9/30/2026
951 Boca	Colorado	TPLP.0000055	Third Party Logistics Provider	4/12/2023	10/31/2026
951 Boca	Minnesota	900285	Third Party Logistics Provider	9/22/2025	10/31/2026
951 Boca	Nevada	WH03470	Wholesaler	7/14/2023	10/31/2026
951 Boca	Arkansas	WD05776	Wholesale Distributor License	11/18/2022	12/31/2026
951 Boca	Illinois	278000183	Wholesale Drug Third Party Logistics Provider	8/29/2023	12/31/2026
951 Boca	Tennessee	8565	Third Party Logistics	12/16/2022	12/31/2026
951 Boca	Texas	1003599	Rx Out of State - Wholesale Distributor	3/23/2023	1/25/2027
951 Boca	Maryland	D07262	Distributor	3/1/2023	5/31/2027
951 Boca	Georgia	PHWH005425	Wholesaler Pharmacy	10/24/2022	6/30/2027
951 Boca	Ohio	0170000107	Third Party Logistics - Category 2	1/25/2023	6/30/2027
951 Boca	Vermont	159.0000210	Third Party Logistics Provider	3/13/2023	7/31/2027
951 Boca	Michigan	5306007334	Wholesale Distributor License	8/16/2023	8/16/2027
951 Boca	New Hampshire	08386	Man/Dist/Whole/Broker	1/17/2023	8/29/2027
951 Boca	Utah	14243289-1714	Pharmacy - Class E Business	9/8/2025	9/30/2027
951 Boca	Arizona	L000447	Third-Party Logistics Provider	11/16/2023	10/31/2027
951 Boca	Missouri	2025046042	Third Party Logistics Provider	10/22/2025	10/31/2027
951 Boca	New Mexico	WD20220404	Temporary - Third Party Logistics Provider Permit	9/3/2025	12/31/2027

IRS.gov

EIN Assistant

Your Progress: 1. Identity 2. Authenticate 3. Addresses 4. Details **5. EIN Confirmation**

Congratulations! Your EIN has been successfully assigned.

EIN Assigned: **88-1175079**

Legal Name: **RELIABLE HEALTHCARE LOGISTICS LLC**

IMPORTANT:

Save and/or print this page and the confirmation letter below for your permanent records.

The confirmation letter below is your official IRS notice and contains important information regarding your EIN.

CLICK HERE for Your EIN Confirmation Letter Help with saving and printing your letter

Once you have saved or printed your letter, click "Continue" to get additional information about using your new EIN. Continue >>

Help Topics

- What if I do not have access to a printer at this time?
- Can I access this letter at a later date?

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See *Specific Instructions* on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Reliable HealthCare Logistics, LLC

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☐ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☑ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) C

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions ☐

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

5 Address (number, street, and apt. or suite no.). See instructions.

951 Clint Moore Road, Suite A

Requester's name and address (optional)

6 City, state, and ZIP code

Boca Raton, FL 33487

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			-			-				

or

Employer identification number

8	8	-	1	1	7	5	0	7	9

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** [signature] **Date** 8-14-2025

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

Dated: July 03, 2025
The following is ORDERED:

Jennie D. Latta
UNITED STATES BANKRUPTCY JUDGE

UNITED STATES BANKRUPTCY COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

IN THE MATTER OF:

RELIABLE HEALTHCARE LOGISTICS, LLC	NO.: 24-20252-JDL
Debtor	CHAPTER 11

ORDER CONFIRMING PLAN OF REORGANIZATION FOR RELIABLE HEALTHCARE LOGISTICS, LLC BY TRUSTED PARTNER PHARMA LOGISTICS LLC AS COMPETING PLAN OF REORGANIZATION

Upon Trusted Partner Pharma Logistics, LLC filed a Competing Plan of Reorganization on April 3, 2025 (ECF No. 318), notice being sent to all creditors and parties in interest with plans and ballots of Reliable Healthcare Logistics, LLC ("Reliable") (ECF No. 321) the Court held confirmation hearing on June 26, 2025 based upon the Tally of Ballots for each competing Plan, objection filed by US Trustee; Limited Objection filed by Creditor Pool 5 Industrial TX, LLC ("Pool 5"); and the Limited Objection filed by BCI IV

Palm Beach CC LLC ("BCI IV") . At the hearing on these matters, the Court found the competing Plan of Reliable according to Tally of Ballots was not capable of confirmation and proceeded on the Tally of Ballots of TPPL and the cram down provisions of 11 U.S.C. Section 1129 for confirmation. After testimony of Benjamin Maziel, witness for TPPL on the elements for confirmation; argument and statements of counsel the Court found TPPL Plan confirmable as orally amended at the hearing and makes findings of fact and conclusions of law as follows:

1. The TPPL Plan complies with the applicable provisions of this title.
2. TPPL complies with applicable provisions of Title 11.
3. TPPL based on testimony of the witness has proposed the Plan in good faith and not by any means forbidden by law.
4. TPPL Plan and witness disclosed all the principals of reorganized company and all payments to be made or to be made acquiring property under the Plan, for services or for costs and expenses in or in connection with the case, or in connection with the Plan and incident to the case, has been approved by, or is subject to the approval of the court as reasonable.
5. TPPL by Plan and witness has disclosed the identity and affiliations of any individual proposed to serve, after confirmation of the plan, as a director, officer, or voting trustee of the debtor, an affiliate of the debtor participating in a joint plan with the debtor under the plan and such appointment to such office is consistent with the interests of creditors and public policy. There is no insider that will be employed or retained by the reorganized debtor.
6. With respect to each impaired class of claims or interest the impaired class has

accepted the TPPL Plan or will receive or retain under the plan on account of such claim or interest property of a value, as of the effective date of the plan, that is not less than the amount that such holder would so receive or retain if the debtor were liquidated under Chapter 7 of this title on such date.

7. Class 3.04 Pre-Petition Unsecured Claim of BCI IV treatment is amended to provide as follows:

Class 3.04 consists of the allowed unsecured claim due to BCI IV Palm Beach, LLC ("BCI") for prepetition rent arrearages in the amount of $550,915.57 (the "Cure Amount") for the lease of non-residential real property located at 951 Clint Moore Road, Boca Raton, Florida (the "Lease"). Upon the Effective Date, the Lease shall be assumed by the Debtor. BCI shall retain its pre-petition security deposit as security for the lease. Upon the Effective Date, BCI shall have an allowed unsecured claim for the Cure Amount and the Debtor shall pay thirty percent (30%) of the Cure Amount. The balance of the Cure Amount shall be paid in 9 equal monthly installments commencing thirty days following the initial payment. Upon written notice from BCI of any default by the Debtor in the payment of the Cure Amount, the Debtor shall have ten (10) days to cure such default. Any defaults with respect to the payment of ongoing rent payments shall be governed by the terms of the Lease.

8. Class 4.04 Pre-Petition Unsecured Claims of Certain Lawsuits is amended to specify in the Encube litigation that the Reorganized Debtor will dismiss the Delaware litigation against Encube with prejudice and Encube will not receive any distribution on its claim against the Debtor; that the Debtor's objection to

Encube's claim is deemed compromised and settled and by this amendment Encube accepts the Plan and all costs associated with such litigation will be paid by each party for their own fees and expenses.

9. Class 5 Interests of Reliable Healthcare Logistics Investments, LLC, pre-petition sole membership interest in the Debtor, is extinguished on the Effective Date. TPPL is contributing new capital to the reorganized debtor in the amount of $500,000 in exchange for one hundred percent (100%) of the membership interest in the reorganized Debtor. The Reorganized Debtor continues to be the same legal entity upon confirmation. The new capital will be paid on or before the Effective Date in full. Class 5

10. All property comprising of the Estate (including causes of action, but excluding property that has been abandoned pursuant to an order of the Bankruptcy Court) shall vest in the Reorganized Debtor, as of the Effective Date, free and clear of all Claims, liens, charges, encumbrances, rights and Interests of creditors and equity security holders. As of the Effective Date, the Reorganized Debtor may operate its business and use, acquire, and dispose of property and settle and compromise Claims or Interests without supervision of the Bankruptcy Court, free of any restrictions of the Bankruptcy Code or Bankruptcy Rules, other than those restrictions expressly imposed by this Plan and Confirmation Order. Except as otherwise provided in any provision of the Plan, upon entry of the Order of Confirmation and pursuant to 11 U.S.C. § 1141(b) and (c), any and all property of the Estate shall vest in the reorganized Debtor free of all liens, security interests, mortgages or other interests in property secured by an Allowed Claim except as

expressly provided for in the Plan. Pursuant to §1146(c), no stamp taxes, transfer tax or Tennessee indebtedness tax or other similar taxes shall be due as a result of the making or delivery of an instrument of transfer pursuant to the Plan.

11. Paragraph K.(4) on Exculpation and Limitation of Liability of TPPL Plan is hereby deleted in full upon objection of US Trustee.

12. Pursuant to this Court's order of March 31, 2025, the proof of claim of Pool 5 Industrial TX, LLC is disallowed. Pool 5 has appealed the Court's order. In the event Pool 5's claim becomes an allowed administrative expense claim or allowed unsecured claim, then such claim shall be deemed incorporated into the Plan with the same priority and classification as such other similarly situated administrative expense claims (Class 1) and/or pre-petition unsecured claims related to rejected/terminated leases (Class 4.01).

13. The Plan will become effective on or before the first business day following fourteen (14) days after the Confirmation Order becomes a Final Order. Upon Final Order the Reorganized Debtor will have full access to all accounts, books and records of Reliable.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED THAT the objections to Plan are denied and the Court makes findings of fact and conclusions of law in regard to the Plan and confirmation as stated above. There is at least one accepting impaired class voting for Plan of TPPL. The TPPL Plan is confirmed based upon the testimony of the witness and amendments as stated herein.

Approved

/s/ Toni Campbell Parker

TONI CAMPBELL PARKER (TN # 6984)
ATTORNEY FOR TPPL
45 North BB King Blvd,. SUITE 201
MEMPHIS, TENNESSEE 38103
Tparker002@att,net
(901) 483-1020

/s/ Carrie Ann Rohrscheib,
Carrie Ann Rohrscheib
Attorney for US Trustee

/s/ R. Campbell Hillyer
R. Campbell Hillyer
Attorney for BCI IV Plam Beach CC LLC and Pool 5D

/s/ David W. Houston IV
David W. Houston IV
Attorney for Encube

/s/ Michael P. Coury
Michael P. Coury
Attorney for Reliable Healthcare Logistics, LLC

CC

Debtpr:

Office of US Trustee
All creditors of this estate and all parties on the mailing matrix of Debtor

4904-7001-6082, v. 1

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH WH03469	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Reliable HealthCare Logistics, LLC

Physical Address: 6 Wheeling Road, Suite A

City: Dayton State: NJ Zip: 08810

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Name of Designated Representative (DR): Carlos Chavez

Licensing Company Email: NJLICENSE@RHCL3PL.COM DR Email: cchavez@rhcl3pl.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Surgical Centers		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Trusted Partner Pharma Logistics, LLC

Corporation/Organization Name: Reliable HealthCare Logistics, LLC

Mailing Address: 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 216 Email: NJlicense@rhcl3pl.com

Contact Person Name: Lizbeth Hernandes

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Reliable HealthCare Logistics, LLC

Facility Name

Benjamin Maizel

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/28/25

Date

Board Use Only	Date Received: 11/12/25	Amount: $1000 CK 012657

An official website of the United States government Here's how you know

FDA

Share Tweet LinkedIn Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Reliable HealthCare Logistics*

Showing 1 to 1 of 1 entries (filtered from 5 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Reliable Healthcare Logistics, LLC	3014193599	118775310	RELABEL; REPACK	6 Wheeling Rd, Ste A, Dayton, New Jersey (NJ) 08810, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Tuesday, Nov 26, 2024

New Search

Reliable
HealthCare Logistics

Entity Organization Chart



Dated: July 03, 2025
The following is ORDERED:

Jennie D. Latta
UNITED STATES BANKRUPTCY JUDGE

UNITED STATES BANKRUPTCY COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

IN THE MATTER OF:

RELIABLE HEALTHCARE LOGISTICS, LLC	NO.: 24-20252-JDL
Debtor	CHAPTER 11

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accepted the TPPL Plan or will receive or retain under the plan on account of such claim or interest property of a value, as of the effective date of the plan, that is not less than the amount that such holder would so receive or retain if the debtor were liquidated under Chapter 7 of this title on such date.

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Approved

/s/ Toni Campbell Parker

TONI CAMPBELL PARKER (TN # 6984)
ATTORNEY FOR TPPL
45 North BB King Blvd,. SUITE 201
MEMPHIS, TENNESSEE 38103
Tparker002@att.net
(901) 483-1020

/s /s/ Carrie Ann Rohrscheib,
Carrie Ann Rohrscheib
Attorney for US Trustee

/s/ R. Campbell Hillyer
R. Campbell Hillyer
Attorney for BCI IV Plam Beach CC LLC and Pool 5D

/s/ David W. Houston IV
David W. Houston IV
Attorney for Encube

/s/ Michael P. Coury
Michael P. Coury
Attorney for Reliable Healthcare Logistics, LLC

CC

Debtpr:

Office of US Trustee
All creditors of this estate and all parties on the mailing matrix of Debtor

4904-7001-6082, v. 1

IRS.gov

EIN Assistant

Your Progress: 1. Identity 2. Authenticate 3. Addresses 4. Details **5. EIN Confirmation**

Congratulations! Your EIN has been successfully assigned.

EIN Assigned: **88-1175079**

Legal Name: **RELIABLE HEALTHCARE LOGISTICS LLC**

IMPORTANT:

Save and/or print this page and the confirmation letter below for your permanent records.

The confirmation letter below is your official IRS notice and contains important information regarding your EIN.

CLICK HERE for Your EIN Confirmation Letter Help with saving and printing your letter

Once you have saved or printed your letter, click "Continue" to get additional information about using your new EIN. Continue >>

Help Topics

- What if I do not have access to a printer at this time?
- Can I access this letter at a later date?

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See *Specific Instructions* on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Reliable HealthCare Logistics, LLC

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☐ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☑ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) C

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions ☐

5 Address (number, street, and apt. or suite no.). See instructions.

951 Clint Moore Road, Suite A

Requester's name and address (optional)

6 City, state, and ZIP code

Boca Raton, FL 33487

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

8	8	–	1	1	7	5	0	7	9

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** [signature] **Date** 8-14-2025

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

Reliable HealthCare Logistics, LLC

List of Officers

Full Name: Benjamin Ephraim Maizel, as sole manager of Reliable HealthCare Logistics, LLC

Title: Chief Executive Officer

DOB: [redacted]

Home Address: [redacted]

Business Address: 951 Clint Moore Road, Suite A, Boca Raton, FL 33487

Email Address: bmaizel@rhcl3pl.com

Phone Number: [redacted]

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RELIABLE HEALTHCARE LOGISTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF AUGUST, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RELIABLE HEALTHCARE LOGISTICS, LLC" WAS FORMED ON THE FOURTH DAY OF MARCH, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203771864

Date: 08-23-25

6655021 8300

SR# 20252605244

You may verify this certificate online at corp.delaware.gov/authver.shtml

CERTIFICATE OF FORMATION
OF
RELIABLE HEALTHCARE LOGISTICS, LLC

This Certificate of Formation of Reliable HealthCare Logistics, LLC is to be filed with the Secretary of State of the State of Delaware pursuant to Section 18-201 of the Delaware Limited Liability Company Act.

1. The name of the limited liability company is Reliable HealthCare Logistics, LLC.

2. The address of the limited liability company's registered office in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of the limited liability company's registered agent at such address shall be National Registered Agents, Inc.

Dated as of this 4th day of March, 2022.

/s/Rebecca Ware
Rebecca Ware, Authorized Person

32593134.1

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:35 PM 03/04/2022
FILED 01:35 PM 03/04/2022
SR 20220886439 - File Number 6655021

State of New Jersey
DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PO BOX 369
TRENTON, N.J. 08625-0369
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

December 28, 2022

Re: Third Party Logistics Providers

Per H.R. 3204, DQSA, Uniform National Policy, Sec. 585 (b)(2) New Jersey does not regulate third-party logistics providers as wholesale distributors. To qualify for a wholesale drug or medical device registration, a facility must conduct regulated wholesale distribution or manufacturing activity as defined in N.J.A.C. 8:21-3A.3, therefore New Jersey does not issue or require registration of third party logistics providers.

Sincerely,
Eric B. Lieberman, Esq.
Project Coordinator, Wholesale Drug Project
Public Health and Food Protection Program

KINSALE INSURANCE COMPANY
2035 Maywill Street, Suite 100
Richmond, VA 23230

DECLARATIONS - LIFE SCIENCES GENERAL LIABILITY - CLAIMS MADE

Policy Number:	0100210519-3
Producer Number:	10014
Name and Address:	RSG Specialty, LLC - Jupiter, FL (AR) 150 S. US Highway 1, 3rd Floor Jupiter, FL 33477

NAMED INSURED:	Reliable Healthcare Logistics LLC
MAILING ADDRESS:	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
POLICY PERIOD:	FROM 10/11/2025 TO 05/12/2026 at 12:01 AM at the address of the named insured as shown above.

IN RETURN FOR THE PAYMENT OF THE PREMIUM, AND SUBJECT TO ALL THE TERMS OF THIS POLICY, WE AGREE WITH YOU TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

LIMITS OF INSURANCE		
Each Claim Limit	$1,000,000	Any one occurrence
Damage to Premises Rented to You Limit	$50,000	Any one premises
Personal and Advertising Injury Limit	$1,000,000	Any one person or organization
General Aggregate Limit	$2,000,000	
Products-Completed Operations Aggregate Limit	$2,000,000	

DEDUCTIBLE(S)	
Each Claim Deductible	$15,000

RETROACTIVE DATE

THIS INSURANCE DOES NOT APPLY TO "BODILY INJURY", "PROPERTY DAMAGE" OR "PERSONAL AND ADVERTISING INJURY" WHICH OCCURS BEFORE THE RETROACTIVE DATE, SHOWN BELOW.		
RETROACTIVE DATE (General Liability):	10/11/2022	at 12:01AM at the address of the named insured as shown above.

DESCRIPTION OF BUSINESS	
DESCRIPTION OF OPERATIONS:	**Pharmaceutical Distributor, Repackager, Relabeler**
BUSINESS TYPE:	Limited Liability Co

ALL PREMISES YOU OWN, RENT OR OCCUPY (If different than the mailing address)	
LOCATION	ADDRESS OF ALL PREMISES YOU OWN, RENT OR OCCUPY
1	1113 Gillingham Lane, Suite A, Sugar Land, TX 77478
2	751 NW 33rd St, Suite 190, Pompano Beach, FL 33064
3	5653 Creekside Pkwy, Lockbourne, OH 43137
4	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
5	6 Wheeling Rd, Dayton, NJ 08810

CLASSIFICATION AND PREMIUM					
CLASS CODE	CLASS DESCRIPTION	BASIS OF PREMIUM	EXPOSURE	RATE	PREMIUM
52343.02.21	Drug, Medicine or Pharmaceutical Preparations Mfg. - other than for animal use	per $1,000 Gross Sales	8,753,425	3.12	$27,298

TOTAL PREMIUM (DEPOSIT PREMIUM):	$27,298
COMPANY FEE:	$300
TOTAL PAYABLE AT INCEPTION:	**$27,598**

POLICY SUBJECT TO AUDIT:	Y	AUDIT PERIOD:	Annual

FORMS AND ENDORSEMENTS
Refer to ADF4001, SCHEDULE OF FORMS

THESE DECLARATIONS, TOGETHER WITH THE COMMON POLICY CONDITIONS AND COVERAGE FORM(S) AND ANY ENDORSEMENT(S), COMPLETE THE ABOVE NUMBERED POLICY.

PHILADELPHIA INSURANCE COMPANIES

Philadelphia Indemnity Insurance Company
One Bala Plaza, Ste. 100
Bala Cynwyd, PA 19004

BOND RIDER

Bond No: PB11499812250

Principal: RELIABLE HEALTHCARE LOGISTICS, LLC

Obligee: THE STATE OF NEVADA

Surety: Philadelphia Indemnity Insurance Company

Effective: August 30, 2025

It is agreed that: Adding Four Locations:

1. 751 NW 33rd Street, Suite 190, Pompano Beach, FL 33064
2. 6 Wheeling Road, Suite A, Dayton, NJ 08810
3. 5653 Creekside Parkway, Suite B, Lockbourne, OH 43137
4. 1113 Gillingham Lane, Suite A, Sugarland, TX 77478

Nothing herein contained shall be held to vary, waive, alter, or extend any of the terms, conditions, agreements or warranties of the above mentioned bond, other than stated as above. Provided, however, that the liability of the company under the attached bond as changed by this order shall not be cumulative.

Signed this 30th **day of** September **. 20** 25 **.**

Principal:

By: _____
Principal Signature

Philadelphia Indemnity Insurance Company

By: _____
John D. Weisbrot **Attorney in Fact**

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 30th day of September 20 25.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
Mortgage loans	980,210	1,060,940
Real estate	45,943	21,033
Derivatives	3,552	-
Other invested assets (cost $219,302 and $201,673)	229,008	226,716
Receivables for securities sold	329	4,072
Cash, cash equivalents and short-term investments	176,533	147,539
Cash and invested assets	11,237,195	10,754,075
Premiums receivable, agents' balances and other receivables	1,166,132	1,108,771
Reinsurance recoverable on paid loss and loss adjustment expenses	63,067	57,589
Accrued investment income	94,377	93,350
Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 6,059,913	$ 5,797,285
Unearned premiums	1,990,597	1,887,004
Reinsurance payable on paid loss and loss adjustment expenses	39,877	35,204
Federal income taxes payable	-	2,352
Ceded reinsurance premiums payable	183,308	152,393
Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
Accrued expenses and other liabilities	54,505	62,438
Total liabilities	8,815,290	8,365,456
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Panciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11499812250

Application/License No. _____

RELIABLE HEALTHCARE LOGISTICS, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 951 CLINT MOORE ROAD, SUITE A, BOCA RATON, FL, 33487 (Address of Applicant/Principal), as PRINCIPAL, and Philadelphia Indemnity Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Bala Plaza, Suite 100 BALA CYNWYD PA 19004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Aug 30, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of September, 20 25.

APPLICANT/PRINCIPAL
RELIABLE HEALTHCARE LOGISTICS, LLC
COMPANY

Authorized Representative

SURETY
Philadelphia Indemnity Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

PHILADELPHIA INDEMNITY INSURANCE COMPANY * CORPORATE SEAL 1927 PENNSYLVANIA

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**, that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 15th day of September, 2025.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

To verify the bond please visit https://www.suretybond.org/validate/?code=fVhD1U1Q4EaXhXA15TXkVADg&transaction=XFkG0VQV16cwheQwBcWVcJCQ

PHILADELPHIA INDEMNITY INSURANCE COMPANY

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(in thousands, except par value and share amounts)

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The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Reliable HealthCare Logistics, LLC — MDEG License # (if applicable): WH03469

Physical Address: 6 Wheeling Road, Suite A

City: Dayton — State: NJ — Zip: 08810

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton — State: FL — Zip: 33487

Telephone: 561-998-3885 Ext 820 — Website: www.reliablehealthcarelogistics.com

Licensing Company Email: NJLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Carlos — Middle: — Last: Chavez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Highstown — State: NJ — Zip: [redacted]

Telephone: 561-998-3885 Ext 307 — Email: NJLicense@rhcl3pl.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Los Angeles Trade Technical College		01/04 - 01/06	
Address	City	State	Zip
400 W Washington Blvd	Los Angeles	CA	90023
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Roosevelt High School		06/89 - 06/91	
Address	City	State	Zip
456 S Mathews St	Los Angeles	CA	90033
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/12 - Present	[redacted]	Highstown	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/2022 - Present	
Business Address	**City**		**State**	**Zip**
6 Wheeling Road, Suite A	Dayton		NJ	08810
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 820	Logistics Manager		6,308	
Description of Duties				
Managing all functions of the warehouse and logistics process - Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			12/21 - 08/2022	
Business Address	**City**		**State**	**Zip**
15 Stults Road	Dayton		NJ	08810
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 820	Logistics Manager		1,512	
Description of Duties				
Managing all functions of the warehouse and logistics process - Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
UDS			09/15 - 10/21	
Business Address	**City**		**State**	**Zip**
9 Corn Road	Dayton		NJ	08810
Phone	**Title**		**Number of Employed Hours**	
	Facility Manager		12,480	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
JAM-N Logistics			01/04 - 09/15	
Business Address	**City**		**State**	**Zip**
2140 E University Drive	Rancho Dominguez		CA	90220
Phone	**Title**		**Number of Employed Hours**	
209-720-7321	General Manager		22,880	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

I, Carlos Chavez, **certify that as the MDEG Administrator for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements):

1. CC Have a high school diploma or its equivalent;
2. CC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CC Will ensure that the operation of the business or facility complies with all applicable federal state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carlos Chavez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

Board Use Only	Date Received: 11/12/25

CARLOS CHAVEZ

[redacted]

PROFILE

Target motivated and results-focused Facilities Management Professional with a verifiable track record in Logistics. 32 yrs. expertise in all areas of warehouse and distribution, inventory management, purchasing, and operations management combined with strong analysis, planning, organizational, and team building abilities that drive positive results. Hands on leadership experience with proven success in the development of sound policies and practices that ensure that the companies financial, business and customer service objectives are achieved.

PROFESSIONAL EXPERIENCE

Reliable HealthCare Logistics, NJ

August 2022 - Present

Facility/Logistics Manager

- Strategic planning and forecasting the day to day facility operations
- Responsible for supervising the receiving, warehousing, and shipping of products.
- Managing all functions of the warehouse and logistics process – including receipt, outbound shipping operations, and inventory control.
- Coach and guide lead supervisors, warehouse and office labor to fulfill best practices
- Preform daily staff meetings

WDSrx, NJ

December 2021 – August 2022

Facility Manager

- Strategic planning and forecasting the day to day facility operations
- Responsible for supervising the receiving, warehousing, and shipping of products.
- Managing all functions of the warehouse and logistics process – including receipt, outbound shipping operations, and inventory control.
- Coach and guide lead supervisors, warehouse and office labor to fulfill best practices

UDS, Dayton/Edison/Cranbury, NJ

September 2015 - October 2021

Facility Manager

- Managed labor scheduling (130 employees)
- Preformed daily staff meetings
- Strategic planning and forecasting the day to day facility operations
- Coached and guided teams of Managers/ Floor Supervisors/ Leads/Warehouse Associates and Office labor for best practices
- Managed and trained team Managers/Floor Supervisors/Leads on all projects
- Responsible for supervising the receiving, warehousing, and shipping of products.
- Managing all functions of the warehouse and logistics process – including receipt, outbound shipping operations, and inventory control.
- Resolved escalated Customer and Employee issues

- Executed final decisions on the hiring and firing of staff
- Overlooked cycle counts
- Overlooked annual physical inventory
- Created SOP's for facilities operations
- Assisted in 2 additional start up facilities
- Daily customer relations communications

JAM-N LOGISTICS, CA & NJ

January 2004 – September 2015

East Coast General Manager

- East Coast company expansion planner
- Sought out and negotiated vendor and freight quotes
- Built labor agency contacts and negotiated best rates
- Sought out, monitored and regulated building security
- Met with potential new clients to discuss their warehousing needs
- Analyzed, evaluated and assisted Regional Sales Manager with customer rate contracts
- Prepared daily financial, efficiency reports for presentation to company president
- Preformed EOM reporting on all accounts
- Monitored monthly P & L reports
- Approved building utility, labor, vendor invoices
- Strategic planning and forecasting the day to day facility operations
- Responsible for supervising the receiving, warehousing, and shipping of products.
- Managing all functions of the warehouse and logistics process – including receipt, outbound shipping operations, and inventory control.
- Managed up to 100 employees at once
- Managed and approved labor scheduling
- Executed final decisions on the hiring and firing of staff
- Preformed daily staff meetings
- Coached and guided lead supervisors, warehouse and office labor to fulfill best practices
- Resolved customer and employee issues
- Assessed and negotiated best rates on all special customer projects preformed
- Overlooked monthly cycle counts
- Overlooked annual physical inventory
- Daily customer relations communications

DAWES TRANSPORT, CA

1998 - 2004

Senior Operations Traffic Controller

- Manage the day-to-day inbound and outbound traffic operations
- Assigned all inbound inventory placement to warehouse staff
- Coordinated closely with the dispatch team to assign 30 local drivers to their daily routes
- Arranged daily pick-up and delivery appointments for 20 line-haul drivers
- Maintained 120 thousand square feet of inventory by performing weekly cycle counts
- Facility key holder with the responsibility of opening the work week every Sunday
- Assisted the OS&D department in research and problem solving
- Responsible for the maintaining and ordering of the warehouse/office supplies

Electro Source, CA

1996 - 1998

Warehouse Project Manager

- Responsible for managing and properly scheduling in 18 employees
- Managed and trained a team on all projects to maintain accuracy and efficiency
- Inventory control by performing cycle counts, bi-weekly audits and sound record keeping
- Daily coordination with carriers in scheduling inbounds and outbounds
- Assisted with picking of product for upcoming projects

UPS, CA

1991 - 1996

Warehouse Associate II

- Loaded and Unloaded 53' trailers
- Lifted, sorted and palletized up to 50lb. packages
- Worked on conveyer belts sorting packages onto proper trailers dock doors
- Responsible for scanning all air packages and uploading the data onto a master computer
- Assisted the Dept. Supervisor in maintaining an efficient work area
- Assisted the OS&D department in research and problem solving

COMPUTER SOFTWARE SKILLS

WMS - 3PL Central & Powerhouse, Vendor Routing, EDI Processing, Outlook, MS Windows, Mac, (Word, Word
Perfect 10, Excel, Power Point), AS400, UPS World Ship, Fed-Ex Ship Manager, Outlook and Internet proficiency

EQUIPMENT SKILLS

All general office and warehouse equipment; conveyor belts, scanning kits, electric pallet wrap machines, sit-down fork lift, stand-up reach lift, cherry picker, electric pallet jack, electric rollers and clamp equipment

LANGUAGE SKILLS

Bi-Lingual in English/ Spanish (Speak, Read & Write).

EDUCATION

Roosevelt High School, CA

- Graduate of 1991

Los Angeles Trade Technical College, CA

- Studied for an Electrician Degree – 2004 – 2006

VOLUNTEER SERVICES

Hightstown Harvest Fair - Logistic Coordinator/ Vendor Compliance
Paws Walk of NJ - Greeter/ Cashier Desk
Tri-State Hightstown Triathlon – Logistic Set-Up

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Reliable HealthCare Logistics, LLC

Pharmacy/Wholesaler License # (if applicable): WH03469

Physical Address: 6 Wheeling Road, Suite A

City: Dayton State: NJ Zip: 08810

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 820 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: NJLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Carlos Middle: Last: Chavez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI[redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Highstown State: NJ Zip: [redacted]

Telephone: 561-998-3885 Ext 820 Email: NJLicense@rhcl3pl.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Los Angeles Trade Technical College		01/04 - 01/06	
Address	**City**	**State**	**Zip**
400 W Washington Blvd	Los Angeles	CA	90023
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Roosevelt High School		06/89 - 06/91	
Address	**City**	**State**	**Zip**
456 S Mathews St	Los Angeles	CA	90033
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/12 - Present	[redacted]	Highstown	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC12/21/			08/2022 - Present	
Business Address		**City**	**State**	**Zip**
6 Wheeling Road, Suite A		Dayton	NJ	08810
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 820	Logistics Manager		6,308	
Description of Duties				
Managing all functions of the warehouse and logistics process - Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			12/21 - 08/2022	
Business Address		**City**	**State**	**Zip**
15 Stults Road		Dayton	NJ	08810
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 820	Logistics Manager		1,512	
Description of Duties				
Managing all functions of the warehouse and logistics process - Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
UDS			09/15 - 10/21	
Business Address		**City**	**State**	**Zip**
9 Corn Road		Dayton	NJ	08810
Phone	**Title**		**Number of Employed Hours**	
	Facility Manager		12,480	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
JAM-N Logistics			01/04 - 09/15	
Business Address		**City**	**State**	**Zip**
2140 E University Drive		Rancho Dominguez	CA	90220
Phone	**Title**		**Number of Employed Hours**	
209-720-7321	General Manager		22,880	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

I, Carlos Chavez, **certify that as the designated representative for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CC I am at least 21 years of age;
3. CC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Carlos Chavez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carlos Chavez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach.

I, Carlos Chavez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/29/2025

Date

Subscribed and Sworn to before me this 29th day of October, 2025.

Notary Public Signature

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Reliable HealthCare Logistics, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03469

Physical Address: 6 Wheeling Road, Suite A

City: Dayton State: NJ Zip: 08810

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: NJLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Benjamin Middle: Ephraim Last: Maizel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dunedin State: FL Zip: [redacted]

Telephon[redacted] Email: bmaizel@rhcl3pl.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fairleigh Dickenson University			
Address	**City**	**State**	**Zip**
1000 River Rd	Teaneck	NJ	07666
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Florida Gainesville			
Address	**City**	**State**	**Zip**
1478 Union Rd	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]	Dunedin	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/01/2025 - Present	
Business Address	**City**	**State**	**Zip**	
951 Clint Moore Road, Suite A	Boca Raton	FL	33487	
Phone	**Title**			
561-998-3885 Ext 207	CEO			
Description of Duties				
CEO of Third-Party Logistics company, focused on the healthcare industry, specifically Generic Pharmaceutical companies.				

Business Name			From - To (MM/YY – MM/YY)	
Trusted Partner Pharma Logistics			01/2023 - Present	
Business Address	**City**	**State**	**Zip**	
3783 Winning Stakes Way	Mason	OH	45040	
Phone	**Title**			
716-553-9641	CEO & Co-Founder			
Description of Duties				
CEO & Co-Founder, Formed specific company to launch a generic focused 3PL				

Business Name			From - To (MM/YY – MM/YY)	
DiRx Inc			03/21 - 07/23	
Business Address	**City**	**State**	**Zip**	
2 TOWER CENTER Blvd Floor 12	East Brunswick	NJ	08816	
Phone	**Title**			
(908) 356-0764	COO			
Description of Duties				
Responsible for all aspects of physical pharmacy, product acquisition, pharmacy team including Customer Service, Outreach and Fulfillment teams, and Compliance.				

Business Name			From - To (MM/YY – MM/YY)	
McKesson			01/2018-03/2020	
Business Address	**City**	**State**	**Zip**	
	Mason	OH		
Phone	**Title**			
	Vice President			
Description of Duties				
Completed Operational, Financial, Customer Service transition to RxCrossroads				

Business Name			From - To (MM/YY – MM/YY)	
RXTPL LLC			01/2012 - 12/2017	
Business Address	**City**	**State**	**Zip**	
	Mason	OH		
Phone	**Title**			
	President			
Description of Duties				
CREATED a 3rd Party Logistics company for pharmaceutical manufacturers. Oversaw all aspects of the company, growing from zero to over 50 international manufacturers and growing business year over year				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Maizel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach.

I, Benjamin Maizel., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/29/2025

Date

Subscribed and Sworn to before me this 29th day of October 2025.

Notary Public Signature

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

(Seal)

From: Lizbeth Hernandes <lhernandes@reliablehealthcarelogistics.com>
Sent: Friday, November 21, 2025 9:20 AM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>; OhioLicense <ohiolicense@rhcl3pl.com>; NJLicense <njlicense@rhcl3pl.com>
Cc: Jessenia Sanchez <jsanchez@rhcl3pl.com>; ochavez@rhcl3pl.com
Subject: Re: Nevada Out-of-State Wholesaler Application-Reliable Healthcare Logistics, LLC

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.
Good afternoon Maria,

Below is the list of employees for each facility that you requested.

OH:

Jessenia Sanchez
Fred Dennis
Michael Bastian
David Haile
Micah Powers
Christopher Walker
Alontai Scott

NJ:

Carlos Chavez
Guadalupe Romero
Luis Diaz Gordillo
Eduard Gomez Rodriguez
Heriberto Lopez Gonzalez
Gerddy Mosquea
Vladimir Munoz Torres
Gerardo Ramos-Camacho
Mariela Peralta

Kind Regards,

Lizbeth Hernandes
Regulatory / Licensing Specialist
Reliable HealthCare Logistics, LLC
951 Clint Moore Road, Suite A
Boca Raton, FL 33487
(561) 998-3885 x216
lhernandes@reliablehealthcarelogistics.com
https://www.reliablehealthcarelogistics.com/

Reliable HealthCare Logistics

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH03467	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Reliable HealthCare Logistics, LLC

Physical Address: 5653 Creekside Parkway, Suite B

City: Lockbourne State: OH Zip: 43137

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Name of Designated Representative (DR): Jessenia Sanchez

Licensing Company Email: OhioLICENSE@RHCL3PL.COM DR Email: jsanchez@rhcl3pl.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Surgical Centers		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Trusted Partner Pharma Logistics, LLC

Corporation/Organization Name: Reliable HealthCare Logistics, LLC

Mailing Address: 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 216 Email: NJlicense@rhcl3pl.com

Contact Person Name: Lizbeth Hernandes

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Reliable HealthCare Logistics, LLC

Facility Name

Benjamin Maizel

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/28/25

Date

Board Use Only	Date Received: 11/12/25	Amount: $100 CK 012658

An official website of the United States government Here's how you know

FDA

Drug Establishments Current Registration Site

✓ Verified mH 11/12/25

New Search

Search Results for *Reliable HealthCare Logistics*

Showing 1 to 1 of 1 entries (filtered from 5 total entries) Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Reliable Healthcare Logistics, LLC	3024552430	118894392	RELABEL; REPACK	5653 Creekside Parkway, Suite B, Lockbourne, Ohio (OH) 43137, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Monday, Dec 16, 2024

New Search

Reliable
HealthCare Logistics

Entity Organization Chart



Reliable HealthCare Logistics, LLC

List of Officers

Full Name: Benjamin Ephraim Maizel, as sole manager of Reliable HealthCare Logistics, LLC

Title: Chief Executive Officer

[redacted]

Home Address [redacted]

Business Address: 951 Clint Moore Road, Suite A, Boca Raton, FL 33487

Email Address: bmaizel@rhcl3pl.com

Phone Number [redacted]

Dated: July 03, 2025
The following is ORDERED:

Jennie D. Latta
UNITED STATES BANKRUPTCY JUDGE

UNITED STATES BANKRUPTCY COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

IN THE MATTER OF:

RELIABLE HEALTHCARE LOGISTICS, LLC	NO.: 24-20252-JDL
Debtor	CHAPTER 11

ORDER CONFIRMING PLAN OF REORGANIZATION FOR RELIABLE HEALTHCARE LOGISTICS, LLC BY TRUSTED PARTNER PHARMA LOGISTICS LLC AS COMPETING PLAN OF REORGANIZATION

Upon Trusted Partner Pharma Logistics, LLC filed a Competing Plan of Reorganization on April 3, 2025 (ECF No. 318), notice being sent to all creditors and parties in interest with plans and ballots of Reliable Healthcare Logistics, LLC ("Reliable") (ECF No. 321) the Court held confirmation hearing on June 26, 2025 based upon the Tally of Ballots for each competing Plan, objection filed by US Trustee; Limited Objection filed by Creditor Pool 5 Industrial TX, LLC ("Pool 5"): and the Limited Objection filed by BCI IV

Palm Beach CC LLC ("BCI IV") . At the hearing on these matters, the Court found the competing Plan of Reliable according to Tally of Ballots was not capable of confirmation and proceeded on the Tally of Ballots of TPPL and the cram down provisions of 11 U.S.C. Section 1129 for confirmation. After testimony of Benjamin Maziel, witness for TPPL on the elements for confirmation; argument and statements of counsel the Court found TPPL Plan confirmable as orally amended at the hearing and makes findings of fact and conclusions of law as follows:

1. The TPPL Plan complies with the applicable provisions of this title.
2. TPPL complies with applicable provisions of Title 11.
3. TPPL based on testimony of the witness has proposed the Plan in good faith and not by any means forbidden by law.
4. TPPL Plan and witness disclosed all the principals of reorganized company and all payments to be made or to be made acquiring property under the Plan, for services or for costs and expenses in or in connection with the case, or in connection with the Plan and incident to the case, has been approved by, or is subject to the approval of the court as reasonable.
5. TPPL by Plan and witness has disclosed the identity and affiliations of any individual proposed to serve, after confirmation of the plan, as a director, officer, or voting trustee of the debtor, an affiliate of the debtor participating in a joint plan with the debtor under the plan and such appointment to such office is consistent with the interests of creditors and public policy. There is no insider that will be employed or retained by the reorganized debtor.
6. With respect to each impaired class of claims or interest the impaired class has

accepted the TPPL Plan or will receive or retain under the plan on account of such claim or interest property of a value, as of the effective date of the plan, that is not less than the amount that such holder would so receive or retain if the debtor were liquidated under Chapter 7 of this title on such date.

7. Class 3.04 Pre-Petition Unsecured Claim of BCI IV treatment is amended to provide as follows:

Class 3.04 consists of the allowed unsecured claim due to BCI IV Palm Beach, LLC ("BCI") for prepetition rent arrearages in the amount of $550,915.57 (the "Cure Amount") for the lease of non-residential real property located at 951 Clint Moore Road, Boca Raton, Florida (the "Lease"). Upon the Effective Date, the Lease shall be assumed by the Debtor. BCI shall retain its pre-petition security deposit as security for the lease. Upon the Effective Date, BCI shall have an allowed unsecured claim for the Cure Amount and the Debtor shall pay thirty percent (30%) of the Cure Amount. The balance of the Cure Amount shall be paid in 9 equal monthly installments commencing thirty days following the initial payment. Upon written notice from BCI of any default by the Debtor in the payment of the Cure Amount, the Debtor shall have ten (10) days to cure such default. Any defaults with respect to the payment of ongoing rent payments shall be governed by the terms of the Lease.

8. Class 4.04 Pre-Petition Unsecured Claims of Certain Lawsuits is amended to specify in the Encube litigation that the Reorganized Debtor will dismiss the Delaware litigation against Encube with prejudice and Encube will not receive any distribution on its claim against the Debtor; that the Debtor's objection to

Encube's claim is deemed compromised and settled and by this amendment Encube accepts the Plan and all costs associated with such litigation will be paid by each party for their own fees and expenses.

9. Class 5 Interests of Reliable Healthcare Logistics Investments, LLC, pre-petition sole membership interest in the Debtor, is extinguished on the Effective Date. TPPL is contributing new capital to the reorganized debtor in the amount of $500,000 in exchange for one hundred percent (100%) of the membership interest in the reorganized Debtor. The Reorganized Debtor continues to be the same legal entity upon confirmation. The new capital will be paid on or before the Effective Date in full. Class 5

10. All property comprising of the Estate (including causes of action, but excluding property that has been abandoned pursuant to an order of the Bankruptcy Court) shall vest in the Reorganized Debtor, as of the Effective Date, free and clear of all Claims, liens, charges, encumbrances, rights and Interests of creditors and equity security holders. As of the Effective Date, the Reorganized Debtor may operate its business and use, acquire, and dispose of property and settle and compromise Claims or Interests without supervision of the Bankruptcy Court, free of any restrictions of the Bankruptcy Code or Bankruptcy Rules, other than those restrictions expressly imposed by this Plan and Confirmation Order. Except as otherwise provided in any provision of the Plan, upon entry of the Order of Confirmation and pursuant to 11 U.S.C. § 1141(b) and (c), any and all property of the Estate shall vest in the reorganized Debtor free of all liens, security interests, mortgages or other interests in property secured by an Allowed Claim except as

expressly provided for in the Plan. Pursuant to §1146(c), no stamp taxes, transfer tax or Tennessee indebtedness tax or other similar taxes shall be due as a result of the making or delivery of an instrument of transfer pursuant to the Plan.

11. Paragraph K.(4) on Exculpation and Limitation of Liability of TPPL Plan is hereby deleted in full upon objection of US Trustee.

12. Pursuant to this Court's order of March 31, 2025, the proof of claim of Pool 5 Industrial TX, LLC is disallowed. Pool 5 has appealed the Court's order. In the event Pool 5's claim becomes an allowed administrative expense claim or allowed unsecured claim, then such claim shall be deemed incorporated into the Plan with the same priority and classification as such other similarly situated administrative expense claims (Class 1) and/or pre-petition unsecured claims related to rejected/terminated leases (Class 4.01).

13. The Plan will become effective on or before the first business day following fourteen (14) days after the Confirmation Order becomes a Final Order. Upon Final Order the Reorganized Debtor will have full access to all accounts, books and records of Reliable.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED THAT the objections to Plan are denied and the Court makes findings of fact and conclusions of law in regard to the Plan and confirmation as stated above. There is at least one accepting impaired class voting for Plan of TPPL. The TPPL Plan is confirmed based upon the testimony of the witness and amendments as stated herein.

Approved

/s/ Toni Campbell Parker

TONI CAMPBELL PARKER (TN # 6984)
ATTORNEY FOR TPPL
45 North BB King Blvd,. SUITE 201
MEMPHIS, TENNESSEE 38103
Tparker002@att,net
(901) 483-1020

/s /s/ Carrie Ann Rohrscheib,
Carrie Ann Rohrscheib
Attorney for US Trustee

/s/ R. Campbell Hillyer
R. Campbell Hillyer
Attorney for BCI IV Plam Beach CC LLC and Pool 5D

/s/ David W. Houston IV
David W. Houston IV
Attorney for Encube

/s/ Michael P. Coury
Michael P. Coury
Attorney for Reliable Healthcare Logistics, LLC

CC

Debtpr:

Office of US Trustee
All creditors of this estate and all parties on the mailing matrix of Debtor

4904-7001-6082, v. 1

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RELIABLE HEALTHCARE LOGISTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF AUGUST, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RELIABLE HEALTHCARE LOGISTICS, LLC" WAS FORMED ON THE FOURTH DAY OF MARCH, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203771864

Date: 08-23-25

6655021 8300

SR# 20252605244

You may verify this certificate online at corp.delaware.gov/authver.shtml

CERTIFICATE OF FORMATION
OF
RELIABLE HEALTHCARE LOGISTICS, LLC

This Certificate of Formation of Reliable HealthCare Logistics, LLC is to be filed with the Secretary of State of the State of Delaware pursuant to Section 18-201 of the Delaware Limited Liability Company Act.

1. The name of the limited liability company is Reliable HealthCare Logistics, LLC.

2. The address of the limited liability company's registered office in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of the limited liability company's registered agent at such address shall be National Registered Agents, Inc.

Dated as of this 4th day of March, 2022.

/s/Rebecca Ware
Rebecca Ware, Authorized Person

32593134.1

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:35 PM 03/04/2022
FILED 01:35 PM 03/04/2022
SR 20220886439 - File Number 6655021

Reliable HealthCare Logistics, LLC

License List

RHL Facility	State	License Number	License Type	License Issue Date	License Expiration Date
RHL OH	Alabama	196454	Third Party Logistics Provider	9/8/2023	12/31/2025
RHL OH	Alaska	202094	Third-Party Logistics Provider	11/8/2022	6/30/2026
RHL OH	Arizona	L000398	Third-Party Logistics Provider	11/16/2023	10/31/2027
RHL OH	Arkansas	WD05759	Wholesale Distributor License	10/21/2022	12/31/2026
RHL OH	California	NPL1389	Nonresident Third Party Logistics Provider	8/24/2023	8/1/2026
RHL OH	Colorado	TPLP.0000059	Third Party Logistics Provider	4/12/2023	10/31/2026
RHL OH	Connecticut	CSW.0005172	Wholesaler of Drugs, Cosmetics & Medical Devices	7/1/2023	6/30/2026
RHL OH	Delaware	A4-0013067	Pharmacy - Wholesale	5/1/2023	9/30/2026
RHL OH	Distric of Columbia	DM250000587	Non-Resident Distributor	9/18/2025	9/30/2026
RHL OH	Florida	02431	Third Party Logistics Provider	3/15/2023	3/31/2027
RHL OH	Georgia	PHWH005565	Wholesaler Pharmacy	5/2/2023	6/30/2027
RHL OH	Illinois	278000185	Wholesale Drug Third Party Logistics Provider	2/14/2023	12/31/2026
RHL OH	Indiana	94000332A	Third Party Logistics Provider	9/19/2025	9/30/2026
RHL OH	Kansas	23-126185	Third Party Logistics Provider	9/12/2025	6/30/2026
RHL OH	Kentucky	TPL00508	Third Party Logistic	8/25/2025	6/30/2026
RHL OH	Louisiana	11723	Distributor of Legend Drugs or Legend Devices	9/10/2025	12/31/2025
RHL OH	Maine	WH70003419	Pharmaceutical Wholesaler	4/7/2023	12/31/2025
RHL OH	Maryland	D07263	Distributor	3/1/2023	5/31/2027
RHL OH	Michigan	5306007335	Wholesale Distributor	8/16/2023	8/16/2027
RHL OH	Minnesota	900224	Third Party Logistics Provider	8/15/2023	10/31/2026
RHL OH	Mississippi	18675 / 16.3a	Third Party Logistics (Non-Resident)	4/19/2023	12/31/2025
RHL OH	Missouri	2025042636	Third Party Logistics Provider	9/29/2025	10/31/2027
RHL OH	Montana	PHA-WDD-LIC-117719	Wholesale Drug Distributor License	3/2/2023	11/30/2025
RHL OH	Nevada	WH03467	Wholesaler	7/14/2023	10/31/2026
RHL OH	New Hampshire	08384	Man/Dist/Whole/Broker	10/31/2022	8/29/2027
RHL OH	New Mexico	WD20220402	Temporary - Third Party Logistics Provider Permit	9/3/2025	12/31/2027
RHL OH	North Carolina	1689	Third Party Logistics	12/12/2022	12/31/2025
RHL OH	Ohio	0170000101	Third Party Logistics - Category 2	10/12/2022	6/30/2027
RHL OH	Oklahoma	88-L-9226	3PL Provider	9/12/2025	9/30/2026
RHL OH	Oregon	DDA-0000636	Drug Distribution Agent	3/13/2023	9/30/2026
RHL OH	Pennsylvania	3000010486	Distributor of Prescription Drugs	3/5/2023	3/31/2026
RHL OH	Rhode Island	DIS03845	Drug Wholesaler - Out of State	12/20/2022	9/30/2026
RHL OH	South Carolina	23420	Non-Resident Third Party Logistics Provider	8/26/2025	6/30/2026
RHL OH	Tennessee	8484	Third Party Logistics	12/16/2022	12/31/2026
RHL OH	Texas	1003598	Rx Out of State - Wholesale Distributor	3/23/2023	12/5/2026
RHL OH	Utah	14243292-1714	Pharmacy - Class E Business	9/8/2025	9/30/2027
RHL OH	Vermont	159.0000273	Third Party Logistics Provider	10/10/2025	7/31/2027
RHL OH	Virginia	0242000245	Nonresident Third Party Logistics Provider	4/13/2023	2/28/2026
RHL OH	West Virginia	3PL0000497	Third Party Logistics Provider	8/29/2025	6/30/2026
RHL OH	Wisconin	10034-45	Wholesale Distributor of Prescription Drugs	9/5/2023	5/31/2026

Ohio Board of Pharmacy

VERIFICATION OF LICENSURE

BUSINESS NAME:	Reliable Healthcare Logistics, LLC
DBA	Reliable HealthCare Logistics, LLC
LOCATION:	5653 Creekside Pkwy Ste B Lockbourne, OH 43137-9317
LICENSE NUMBER:	0170000101
TYPE OF LICENSE:	Third-Party Logistics - Category 2
ORIGINAL LICENSURE DATE:	October 12, 2022
EXPIRATION DATE:	June 30, 2027
CURRENT LICENSE STATUS:	Active
CURRENT LICENSE SUB STATUS:	N/A
BOARD ACTION:	No (If Board Action is "Yes", you may find more information at elicense.ohio.gov)
DATE OF VERIFICATION:	10/8/2025

Grant Miller
Licensing Administrator
Ohio Board of Pharmacy

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Ohio Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2027.

Reliable Healthcare Logistics, LLC

Reliable HealthCare Logistics, LLC

5653 Creekside Pkwy Ste B

Lockbourne, OH 43137-9317

License Number: 0170000101

License Type: Third-Party Logistics - Category 2

Sub-Category: 3PL – Third-Party Logistics

Expiration Date: June 30, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Jesseria Sanchez	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

KINSALE INSURANCE COMPANY
2035 Maywill Street, Suite 100
Richmond, VA 23230

DECLARATIONS - LIFE SCIENCES GENERAL LIABILITY - CLAIMS MADE

Policy Number: 0100210519-3
Producer Number: 10014
Name and Address: RSG Specialty, LLC - Jupiter, FL (AR)
150 S. US Highway 1, 3rd Floor
Jupiter, FL 33477

NAMED INSURED:	Reliable Healthcare Logistics LLC
MAILING ADDRESS:	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
POLICY PERIOD:	FROM 10/11/2025 TO 05/12/2026 at 12:01 AM at the address of the named insured as shown above.

IN RETURN FOR THE PAYMENT OF THE PREMIUM, AND SUBJECT TO ALL THE TERMS OF THIS POLICY, WE AGREE WITH YOU TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

LIMITS OF INSURANCE		
Each Claim Limit	$1,000,000	Any one occurrence
Damage to Premises Rented to You Limit	$50,000	Any one premises
Personal and Advertising Injury Limit	$1,000,000	Any one person or organization
General Aggregate Limit	$2,000,000	
Products-Completed Operations Aggregate Limit	$2,000,000	

DEDUCTIBLE(S)	
Each Claim Deductible	$15,000

RETROACTIVE DATE

THIS INSURANCE DOES NOT APPLY TO "BODILY INJURY", "PROPERTY DAMAGE" OR "PERSONAL AND ADVERTISING INJURY" WHICH OCCURS BEFORE THE RETROACTIVE DATE, SHOWN BELOW.		
RETROACTIVE DATE (General Liability):	10/11/2022	at 12:01AM at the address of the named insured as shown above.

DESCRIPTION OF BUSINESS	
DESCRIPTION OF OPERATIONS:	Pharmaceutical Distributor, Repackager, Relabeler
BUSINESS TYPE:	Limited Liability Co

ALL PREMISES YOU OWN, RENT OR OCCUPY (If different than the mailing address)	
LOCATION	ADDRESS OF ALL PREMISES YOU OWN, RENT OR OCCUPY
1	1113 Gillingham Lane, Suite A, Sugar Land, TX 77478
2	751 NW 33rd St, Suite 190, Pompano Beach, FL 33064
3	5653 Creekside Pkwy, Lockbourne, OH 43137
4	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
5	6 Wheeling Rd, Dayton, NJ 08810

CLASSIFICATION AND PREMIUM					
CLASS CODE	CLASS DESCRIPTION	BASIS OF PREMIUM	EXPOSURE	RATE	PREMIUM
52343.02.21	Drug, Medicine or Pharmaceutical Preparations Mfg. - other than for animal use	per $1,000 Gross Sales	8,753,425	3.12	$27,298

TOTAL PREMIUM (DEPOSIT PREMIUM):	$27,298
COMPANY FEE:	$300
TOTAL PAYABLE AT INCEPTION:	**$27,598**

POLICY SUBJECT TO AUDIT:	Y	AUDIT PERIOD:	Annual

FORMS AND ENDORSEMENTS
Refer to ADF4001, SCHEDULE OF FORMS

THESE DECLARATIONS, TOGETHER WITH THE COMMON POLICY CONDITIONS AND COVERAGE FORM(S) AND ANY ENDORSEMENT(S), COMPLETE THE ABOVE NUMBERED POLICY.

PHILADELPHIA INSURANCE COMPANIES

Philadelphia Indemnity Insurance Company
One Bala Plaza, Ste. 100
Bala Cynwyd, PA 19004

BOND RIDER

Bond No: PB11499812250

Principal: RELIABLE HEALTHCARE LOGISTICS, LLC

Obligee: THE STATE OF NEVADA

Surety: Philadelphia Indemnity Insurance Company

Effective: August 30, 2025

It is agreed that: Adding Four Locations:

1. 751 NW 33rd Street, Suite 190, Pompano Beach, FL 33064
2. 6 Wheeling Road, Suite A, Dayton, NJ 08810
3. 5653 Creekside Parkway, Suite B, Lockbourne, OH 43137
4. 1113 Gillingham Lane, Suite A, Sugarland, TX 77478

Nothing herein contained shall be held to vary, waive, alter, or extend any of the terms, conditions, agreements or warranties of the above mentioned bond, other than stated as above. Provided, however, that the liability of the company under the attached bond as changed by this order shall not be cumulative.

Signed this 30th **day of** September **. 20** 25 .

Principal:

By: _____
Principal Signature

Philadelphia Indemnity Insurance Company

By: _____
John D. Weisbrot **Attorney in Fact**

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 30th day of September 20 25.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
Mortgage loans	980,210	1,060,940
Real estate	45,943	21,033
Derivatives	3,552	-
Other invested assets (cost $219,302 and $201,673)	229,008	226,716
Receivables for securities sold	329	4,072
Cash, cash equivalents and short-term investments	176,533	147,539
Cash and invested assets	11,237,195	10,754,075
Premiums receivable, agents' balances and other receivables	1,166,132	1,108,771
Reinsurance recoverable on paid loss and loss adjustment expenses	63,067	57,589
Accrued investment income	94,377	93,350
Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 6,059,913	$ 5,797,285
Unearned premiums	1,990,597	1,887,004
Reinsurance payable on paid loss and loss adjustment expenses	39,877	35,204
Federal income taxes payable	-	2,352
Ceded reinsurance premiums payable	183,308	152,393
Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
Accrued expenses and other liabilities	54,505	62,438
Total liabilities	8,815,290	8,365,456
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 16, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11499812250

Application/License No. _____

RELIABLE HEALTHCARE LOGISTICS, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 951 CLINT MOORE ROAD, SUITE A, BOCA RATON, FL, 33487 (Address of Applicant/Principal), as PRINCIPAL, and Philadelphia Indemnity Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Bala Plaza, Suite 100 BALA CYNWYD PA 19004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Aug 30, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of September, 20 25.

APPLICANT/PRINCIPAL
RELIABLE HEALTHCARE LOGISTICS, LLC
COMPANY

Authorized Representative

SURETY
Philadelphia Indemnity Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

PHILADELPHIA INDEMNITY INSURANCE COMPANY * CORPORATE SEAL 1927 PENNSYLVANIA

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed $50,000,000.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**, that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 15th day of September, 2025.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

To verify the bond please visit https://www.suretybond.org/validate/?code=fVhD1U1Q4EaXhXA15TXkVADg&transaction=XFkG0VQV16owheQwRcyYdJCQ

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
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Real estate	45,943	21,033
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Receivables for securities sold	329	4,072
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Cash and invested assets	11,237,195	10,754,075
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Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

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Liabilities:		
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Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
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Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Reliable HealthCare Logistics, LLC — MDEG License # (if applicable): WH03467

Physical Address: 5653 Creekside Parkway, Suite B

City: Lockbourne — State: OH — Zip: 43137

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton — State: FL — Zip: 33487

Telephone: 561-998-3885 Ext 808 — Website: www.reliablehealthcarelogistics.com

Licensing Company Email: OHIOLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Jessenia — Middle: — Last: Sanchez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Lancaster — State: OH — Zip: [redacted]

Telephone: 561-998-3885 Ext 808 — Email: ohiolicense@rhcl3pl.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Turabo University		1994-2000	
Address	**City**	**State**	**Zip**
Street 181 KM 3.3	Gurabo	PR	00778
Diploma/Degree obtained, if any			
Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Maria Cruz Buitrago		1994	
Address	**City**	**State**	**Zip**
42C5+3x4, PR-745	San Lorenzo	PR	00754
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03-20 Present	[redacted]	Lancaster	OH	[redacted]
02/19 - 03/2020		Lancaster	OH	
022019		San Lorenzo	PR	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/11/2022 - Present	
Business Address		**City**	**State**	**Zip**
5653 Creekside Parkway, Suite B		Lockbourne	OH	43137
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 808	Logistics Manager		6,308	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			12/21 - 08/2022	
Business Address		**City**	**State**	**Zip**
5653 Creekside Parkway, Suite B		Lockbourne	OH	43137
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 808	Logistics Manager		1,512	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Crowley Caribbean Logistics			03/2012 - 01/2019	
Business Address		**City**	**State**	**Zip**
Carretera 165 KM 2.4 Edificio 13		San Juan	PR	00965
Phone	**Title**		**Number of Employed Hours**	
787-793-8575	Freight Broker Transportation			
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
F & R Construction				
Business Address		**City**	**State**	**Zip**
1010 C. Harvard		San Juan	PR	00927
Phone	**Title**		**Number of Employed Hours**	
787-753-7010	Administrative Assistance			
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11.05.2025
Date

I, Jessenia Sanchez, **certify that as the MDEG Administrator for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements):

1. JS Have a high school diploma or its equivalent;
2. JS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessenia Sanchez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11·05·2025
Date

Board Use Only	Date Received: 11/12/25

[redacted]

Account Coordination, Freight Broker, Land Transportation, Facility Manager

Logistic Coordination... 3PL Domination Area... Trained on Supply Chain... Account Management

Highly qualified, experienced logistics professional with exceptional communication skills and strong leadership style to effectively solve problems and deliver superior performance. Freight Broker Land Transportation with talent for coordination and quote information. Strong knowledge of Logistic Area, Logistic Specialist, Driver's Coordination, Supply Chain and Customer Service. Vast experience in all aspects of loading and transportation material and documentation requirements. Proficient in leveraging import and export knowledge for accurate preparation of shipping documents and arranging for cargo pick up. Ability to work with and meet deadlines, prioritization and organization of workload. Able to work independently with minimal supervision. Interacts and communicates effectively with colleagues, vendors and clients.

Recipient of the **Crowley Tops Award** for High Performance, Security, Integrity and Commitment during seven years employment. Designated as "Super User on Cargo wise" during the implementation of a state-of-the-art Training System for all employees in 2016.

Educational Background

Business Administration
Turabo University, Gurabo.P.R.
(1994)

Core Strengths

- Strong Initiative
- Problem Solving
- Team Player
- Detail Oriented/ Organized
- Analytical Skills
- Customer Service Oriented
- Accountability

References

- **Enrique Figueroa, HR Director**
- Crowley Logistics
- [redacted]
- **Ayesha Diaz, Director of Operations**
- Allied Logistic
- [redacted]
- **Patricia Catala, Supervisor**
- Crowley Logistics.
- [redacted]

Professional Experience

Facility Manager — Reliable HealthCare Logistics LLC
Lockbourne, OH — 2022 - Present

- Responsible for full cycle account management. Daily order monitoring, problem solving, project status for clients.
- Primary point-of-contact for clients. Develop a trusted working relationship and deliver resolutions.
- Maintain Inventory Control reports.
- Schedule shipments based on client requirements. Address post-order issues regarding billing and delivery.
- Follow Reliable Standard Operating Procedures.
- Identify internal process improvements to maximize efficiency.
- Communicate and collaborate internally regarding on-time shipments, follow escalation protocol.

Account Coordinator — Woodfield Distribution
Lockbourne, OH — 2020 - 2022

- Responsible for full cycle account management. Daily order monitoring, problem solving, project status for clients.
- Primary point-of-contact for clients. Develop a trusted working relationship and deliver resolutions.
- Maintain Inventory Control reports.
- Schedule shipments based on client requirements. Address post-order issues regarding billing and delivery.
- Follow Reliable Standard Operating Procedures.

- Identify internal process improvements to maximize efficiency.
- Communicate and collaborate internally regarding on-time shipments, follow escalation protocol.

Freight Broker Crowley Caribbean Logistics, LLC
San Juan, Puerto Rico 2012 - 2020

- Quote potential customers on the price of freight brokerage
- Coordinate with freight forwarders to expedite international shipments
- Acted as a liaison between freight companies and shippers
- Double checked shipments and according client's orders
- Negotiated rates based on current market trends
- Retrieved stores items and traced last shipments when necessary
- Determined shipping methods and prepared bill of landing, invoices and other shipping documents
- Validated load plans, cargo cleanliness and transportation documentation
- Attached address labels, identification codes and shipping instructions to containers
- Aided senior leadership with report generation to utilize process improvements
- Planned and prioritized day to day shipments and billing in collaboration with warehouse and sales team
- Communicated with customers and management to report delays, emergencies, weather challenges and carrier's schedule changes. Preparation of monthly reporting
- Monitored and organized logistics documents including bill of lading, delivery receipts, packing and loading list and loading tags
- Coordinate import and export operations to ensure adherence to schedules and deadlines
- Resolved customer concerns in a timely manner and improve process integration and work flow
- Kept deliveries on track and provided timely status updates
- Create and validate inbound-outbound

Logistic Coordinator Specialist Crowley Caribbean Logistics, LLC
2014 - 2017

Logistic Warehouse Clerk Crowley Caribbean Logistics, LLC
2012 - 2014

Administrative Assistance F & R Construction Group, Inc.
San Juan, Puerto Rico 2000 - 2012

- Processed financial documents including contracts, expense report and invoices
- Created and maintained spreadsheets and developed administrative and logistical reports
- Liaised between internal and external stakeholders, providing updated project status and performance reports
- Monitored daily and weekly schedules and monthly calendar obligations for over Architects, Project Managers, Project Engineers, layers, project owners and construction staff
- Verify and review forms and reports for compliance with company regulations and procedures. Enter and track information into appropriate computer programs

Proficient with MS Office (Word, Excel, Power Point and Outlook), T.M.W, Cargo wise, CICS
Fluent in English and Spanish

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Reliable HealthCare Logistics, LLC

Pharmacy/Wholesaler License # (if applicable): WH03467

Physical Address: 5653 Creekside Parkway, Suite B

City: Lockbourne State: OH Zip: 43137

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 808 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: OHIOLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Jessenia Middle: Last: Sanchez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Lancaster State: OH Zip: [redacted]

Telephone: 561-998-3885 Ext 808 Email: ohiolicense@rhcl3pl.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Turabo University		1994-2000	
Address	City	State	Zip
Street 181 KM 3.3	Gurabo	PR	00778
Diploma/Degree obtained, if any			
Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Maria Cruz Buitrago		1994	
Address	City	State	Zip
42C5+3x4, PR-745	San Lorenzo	PR	00754
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03-20 Present	[redacted]	Lancaster	OH	[redacted]
02/19 - 03/2020		Lancaster	OH	
022019		San Lorenzo	PR	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/11/2022 - Present	
Business Address		City	State	Zip
5653 Creekside Parkway, Suite B		Lockbourne	OH	43137
Phone	Title		Number of Employed Hours	
561-998-3885 Ext 808	Logistics Manager		6,308	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			12/21 - 08/2022	
Business Address		City	State	Zip
5653 Creekside Parkway, Suite B		Lockbourne	OH	43137
Phone	Title		Number of Employed Hours	
561-998-3885 Ext 808	Logistics Manager		1,512	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Crowley Caribbean Logistics			03/2012 - 01/2019	
Business Address		City	State	Zip
Carretera 165 KM 2.4 Edificio 13		San Juan	PR	00965
Phone	Title		Number of Employed Hours	
787-793-8575	Freight Broker Transportation			
Description of Duties				
Responsible for all the drivers route/Inbound & Outbound orders				

Business Name			From - To (MM/YY – MM/YY)	
F & R Construction				
Business Address		City	State	Zip
1010 C. Harvard		San Juan	PR	00927
Phone	Title		Number of Employed Hours	
787-753-7010	Administrative Assistance			
Description of Duties				
Payroll, Subcontractor agreements, Legal contracts, Accounting.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11.05.2025
Date

I, Jessenia Sanchez, certify that as the designated representative for

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JS I am at least 21 years of age;
3. JS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jessenia Sanchez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11.05.2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessenia Sanchez

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/5/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida., ss. County of Palm Beach.

I, Jessenia Sanchez., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/5/2025

Date

Subscribed and Sworn to before me this 5th day of November

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Reliable HealthCare Logistics, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03467

Physical Address: 5653 Creekside Parkway, Suite B

City: Lockbourne State: OH Zip: 43137

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: OHIOLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Benjamin Middle: Ephraim Last: Maizel

Alias(es, nicknames, name changes, etc.):

Date of Bi[redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addre[redacted]

City: Dunedin State: FL Zip [redacted]

Telephone[redacted] Email: bmaizel@rhcl3pl.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fairleigh Dickenson University			
Address	**City**	**State**	**Zip**
1000 River Rd	Teaneck	NJ	07666
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Florida Gainesville			
Address	**City**	**State**	**Zip**
1478 Union Rd	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]	Dunedin	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/01/2025 - Present	
Business Address	**City**		**State**	**Zip**
951 Clint Moore Road, Suite A	Boca Raton		FL	33487
Phone	**Title**			
561-998-3885 Ext 207	CEO			
Description of Duties				
CEO of Third-Party Logistics company, focused on the healthcare industry, specifically Generic Pharmaceutical companies.				

Business Name			From - To (MM/YY – MM/YY)	
Trusted Partner Pharma Logistics			01/2023 - Present	
Business Address	**City**		**State**	**Zip**
3783 Winning Stakes Way	Mason		OH	45040
Phone	**Title**			
716-553-9641	CEO & Co-Founder			
Description of Duties				
CEO & Co-Founder, Formed specific company to launch a generic focused 3PL				

Business Name			From - To (MM/YY – MM/YY)	
DiRx Inc			03/21 - 07/23	
Business Address	**City**		**State**	**Zip**
2 TOWER CENTER Blvd Floor 12	East Brunswick		NJ	08816
Phone	**Title**			
(908) 356-0764	COO			
Description of Duties				
Responsible for all aspects of physical pharmacy, product acquisition, pharmacy team including Customer Service, Outreach and Fulfillment teams, and Compliance.				

Business Name			From - To (MM/YY – MM/YY)	
McKesson			01/2018-03/2020	
Business Address	**City**		**State**	**Zip**
	Mason		OH	
Phone	**Title**			
	Vice President			
Description of Duties				
Completed Operational, Financial, Customer Service transition to RxCrossroads				

Business Name			From - To (MM/YY – MM/YY)	
RXTPL LLC			01/2012 - 12/2017	
Business Address	**City**		**State**	**Zip**
	Mason		OH	
Phone	**Title**			
	President			
Description of Duties				
CREATED a 3rd Party Logistics company for pharmaceutical manufacturers. Oversaw all aspects of the company, growing from zero to over 50 international manufacturers and growing business year over year				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Maizel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, Benjamin Maizel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/29/2025

Date

Subscribed and Sworn to before me this 29th day of November, 2025

Notary Public Signature

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

(Seal)

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0170000101

Reliable Healthcare Logistics, Llc

5653 Creekside Pkwy Ste B
Lockbourne, OH 43137-9317
Franklin County

Third-Party Logistics - Category 2

DDD Inspection Updated 1/15/2025

September 24, 2025

License 0170000101 - Reliable Healthcare Logistics, Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Jessica Harris
Start 9/24/2025 10:00 AM
End 9/24/2025 11:28 AM

Organization

Name
Reliable Healthcare Logistics, Llc

License Type
Third-Party Logistics - Category 2

Category

License Number
0170000101

Business Type
3PL - Third-Party Logistics

DEA Number

Responsible Person
Jessenia Sanchez

Hours of Operation
Monday-Friday 8:30am-5pm

Contact

Address
5653 Creekside Pkwy Ste B
Lockbourne, OH 43137-9317
Franklin County

Primary Number
(561) 998-3885

Fax Number
(561) 998-3886

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Bejamin Maizel		Owner			
Jessenia Sanchez		Responsible Person			
Krysta Sinisgalli					

1) General Inspection Information

1) Document personnel conducting inspection

Observation
Agent Jessica Harris

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description and Type

Observation
Facility is a Category 2-3PL and does not own the drug stock. Has approximately 11 clients they kept drug stock for. Facility provided the current customer list. Facility is working to rebuild customer base after bankruptcy with previous owner. Product consists of prescription medication and over-the -counter medication. Approximately 70,000 sqft building. Badge access set by job duties and those who need appropriate access. Guest sign in and are escorted by facility staff.

4) Have there been any changes in the DDD's ownership, business name or trade name, category, or address without submitting a new application to the Board?

Yes

Observation
Previous owner filed bankruptcy. Facility utilized proper channels with the Board to notify change in ownership. Reliable Healthcare Logistics is currently owned by Bejamin Maizel.

5) Does the DDD have a valid registration issued by the Drug Enforcement Administration?

No

Observation
This facility is a Category 2 and does not have controlled substances.

6) Is the Responsible Person present during the inspection?

Yes

7) How often is the Responsible Person at the DDD?

Observation
The Responsible Person is on-site approximately 5 days per week.

4.2) Report of theft or sig loss of dang drugs, controlled subs, and drug documents (OAC 4729:6-3-02)

1) Did the distributor of dangerous drugs experience a theft or significant loss of dangerous drugs, controlled substances, and drug documents?

No

Observation
OAC 4729:6-3-02 | Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. (effective October 31, 2021)

(A) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the administrative code shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss;

(B) The theft or significant loss of controlled substances by a licensee shall be reported by using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss.

(1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.

4.4) Verification of licensure prior to sale or purchase (OAC 4729:6-3-04)

4) THIRD-PARTY LOGISTICS PROVIDER: Does the 3PL verify the location dangerous drugs were sold to is licensed as a TDDD or DDD?

Yes

Observation
Discussed logistic management system, DateX, will not allow shipment if the customer does not have the appropriate license or if the product is twelve (12) months to expire.

4.6) Controlled substances inventory requirements (OAC 4729:6-3-06)

1) Has the DDD completed a controlled substance inventory?

Not Applicable: Category 2 DDD

12.1) Third Party Logistics Providers - General Operations (OAC 4729:6-11-01)

1) Are areas where dangerous drugs are stored, warehoused, handled, held, offered, marketed or displayed appropriately constructed and maintained?

Yes. Areas are of suitable size and construction to facilitate cleaning, maintenance, and proper operations.

Yes, there are storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

Yes, there is a quarantine area for storage of dangerous drugs that are damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

Yes, the facility is maintained in a clean and orderly condition.

Yes, the facility is free from infestation by insects, rodents, birds, or vermin of any kind.

Yes, the 3PL is registered as a business entity with the appropriate state or local authority(s) and operates out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

2) Are adulterated drugs stored utilizing proper methods?

Yes, adulterated drugs are stored in a separate and secure area apart from the storage of drugs used for distribution/sale.

Yes, adulterated drugs are stored no longer than 2 years from the date of adulteration/expiration.

Yes, adulterated drugs are stored in a manner that prohibits access by unauthorized people.

3) Are dangerous drugs destroyed utilizing proper methods of disposal and following proper record keeping requirements?

Other.

Observation
Facility does not conduct on-site destruction of dangerous drugs. Facility utilizes US Waste Industries. Drug records are kept for all dangerous drug destruction.

5) Is the facility secured?

Yes, access from outside the premises is kept to a minimum and is well controlled.

Yes, the outside perimeter of the premises is well lit.

Yes, entry into areas where dangerous drugs are stored is limited to authorized personnel.

Yes, all facilities where dangerous drugs are stored are equipped with an alarm system to detect unauthorized entry after hours.

Yes, the facility is equipped with a security system that provides protection against theft and diversion.

Yes, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

Observation
The facility utilizes Johnson Controls for alarm, camera, and badge access.

6) Is drug stock stored in an appropriate temperature monitored environment?

Yes, dangerous drugs are stored under conditions of labeling or with USP/NF requirements.

Yes, when storage requirements are not established for a drug, the drug is maintained at a controlled room temperature.

Yes, the facility is equipped with manual electromechanical, or electronic temperature and humidity recording equipment.

Yes, manual or electronic logs are utilized to document proper storage of dangerous drugs.

Yes, temperature/humidity documentation is readily retrievable.

Observation

The facility utilizes ELPRO Temperature monitoring and records are readily retrievable.

OAC 4729:6-11-01 | Third-party logistics providers- general operations | Effective 8/31/2024

(D) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs. Temperature and humidity documentation shall be made readily retrievable and maintained for a period of not less than five years from the last documented temperature and humidity reading.

7) Are incoming and outgoing shipments of dangerous drugs examined for contamination or damage to the contents?

Yes, upon receipt outside shipping containers are visually examined.

Yes, examination of outside shipping containers is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

Yes, outgoing shipments are visually examined.

Yes, examination of outgoing shipments is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

8) Are returned, damaged, and adulterated dangerous drugs handled appropriately?

Yes, drugs are quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

Yes, if the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity the drug is destroyed or returned.

Yes, drugs of questionable safety, identity, strength, quality or purity are examined or tested to prove the drug meets appropriate safety standards.

Yes, When determining a drugs safety, identity, strength, quality or purity the drug distributor considers the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

Observation

All pallets and boxes examined. If damaged a photo is taken and documents of the damage are forwarded to the customers. A file is kept on site. Product is kept in quarantine area to wait customer instructions.

9) Does the third party logistics provider have, maintain and adhere to written policies and procedures?

Yes, there are policies and procedures for the receipt of drugs.

Yes, there are policies and procedures for drug security.

Yes, there are policies and procedures for drug storage.

Yes, there are policies and procedures for drug inventory.

Yes, there are policies and procedures for drug distribution.

Yes, there are policies and procedures for identifying, recording and reporting losses or thefts of drugs.

Yes, there are policies and procedures for correcting all errors and inaccuracies in inventories.

Yes, policies and procedures are routinely maintained, reviewed, and updated.

Yes, policies and procedures are adhered to by staff.

Yes, there is a procedure to protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

Yes, there is a procedure to ensure that any adulterated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed.

Yes, there is a procedure to provide written documentation of the disposition of adulterated dangerous drug for five years.

Observation

Observed.

10) Does the 3PL have a procedure to be followed for handling recalls and withdrawals of dangerous drugs?

Yes, the procedure addresses handling action initiated at the request of the FDA, or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy.

Yes, the procedure addresses any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.

Yes, the procedure addresses any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

Observation
Discussed.

11) Do employees have appropriate education, experience and training to assume responsibility for positions related to 3PL compliance?

Yes.

Observation
New employees participate in a two week training and are educated on the standard operating procedures.

13) Notice of entry and inspection.

Observation
OAC 4729:6-11-01
(J) Third-party logistics providers shall permit properly identified and authorized state board of pharmacy employees and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

15) Has the facility notified the board of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs?

No, the facility has not constructed any new facilities, work or storage areas.

Observation
OAC 4729:6-11-01 | Third-party logistics providers- general operations | Effective 8/31/2024
(L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs.

16) Do storage, transportation and delivery methods used by agents of the 3PL meet the security standards?

Yes, common or contract carriers provide adequate security to guard against in-transit losses.

Yes, when distributing drugs through agents, 3PL provides and requires adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Observation
The facility utilizes UPS, Fed Ex, Old Dominion, Estes

12.2) Third Party Logistics Providers - Record Keeping (4729:6-11-02)

1) Does the 3PL maintain inventories and records for all transactions regarding the receipt of dangerous drugs?

Yes, records include the source of the drug, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.

Yes, records include the name, national drug code, and quantity of the drugs received distributed, sold, disposed, or returned.

Yes, records include the dates of receipt, sale, and distribution of the drugs.

Yes, records contain the name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.

Yes, the system prevents the sale or other distribution of dangerous drugs to unauthorized persons.

2) Does the 3PL maintain inventories and records for all transactions regarding the sale of dangerous drugs?

Yes, records include the source of the drug, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.

Yes, records include the name, national drug code, and quantity of the drugs received distributed, sold, disposed, or returned

Yes, records include the dates of receipt, sale, and distribution of the drugs.

Yes, records contain the name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.

Yes, the system prevents the sale or other distribution of dangerous drugs to unauthorized persons.

3) Does the 3PL maintain inventories and records for all transactions regarding the distribution of dangerous drugs?

Yes, records include the source of the drug, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.

Yes, records include the name, national drug code, and quantity of the drugs received distributed, sold, disposed, or returned

Yes, records include the dates of receipt, sale, and distribution of the drugs.

Yes, records contain the name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.

Yes, the system prevents the sale or other distribution of dangerous drugs to unauthorized persons.

4) Does the 3PL maintain inventories and records for all transactions regarding the other disposition of dangerous drugs?

Yes, records include the source of the drug, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.

Yes, records include the name, national drug code, and quantity of the drugs received distributed, sold, disposed, or returned

Yes, records include the dates of receipt, sale, and distribution of the drugs.

Yes, records contain the name and principal address of the purchaser or receiver and the address of the location where the drugs were shipped.

Yes, the system prevents the sale or other distribution of dangerous drugs to unauthorized persons.

Observation

OAC 4729:6-11-02 | Third-party Logistics Providers- Recordkeeping | Effective 8/31/2024

(A) Third party Third-party DATE: 07/11/2024 2:14 PM Third party Third-party logistics providers shall establish and maintain inventories and records of all transactions regarding the receipt, sale, and distribution or other disposition of dangerous drugs.
(1) The records shall include, but not be limited to, the following information:
(a) The source of the drugs, including the name and principle principal address of the seller or transferor, and the address of the location from which the drugs were shipped.
(b) The name, national drug code, and quantity of the drugs received, distributed, sold, disposed, or returned. (c) The dates of receipt, sale, and distribution of the drugs.
(d) The name and principle principal address of the purchaser or receiver and the address of the location where the drugs were shipped.
(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

5) Are records readily retrievable for inspection and copying for a period for 5 years?

Yes, records are readily retrievable for inspection and copying.

Yes, records are maintained for 5 years.

Observation

Observed electronic records.

6) Does the in state 3PL store records at a location other than the place licensed by the board?

No, the 3PL does not store records at an offsite location.

7) Does the 3PL follow the recordkeeping requirements for all damaged, deteriorated, misbranded, or adulterated dangerous drugs?

Yes.

16) Inspection Affirmation

1) Inspection Affirmation

Observation

*This document only addresses compliance with the rules or laws specifically identified above.

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Jessenia Sanchez

(signature)

From: Lizbeth Hernandes <lhernandes@reliablehealthcarelogistics.com>
Sent: Friday, November 21, 2025 9:20 AM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>; OhioLicense <ohiolicense@rhcl3pl.com>; NJLicense <njlicense@rhcl3pl.com>
Cc: Jessenia Sanchez <jsanchez@rhcl3pl.com>; ochavez@rhcl3pl.com
Subject: Re: Nevada Out-of-State Wholesaler Application-Reliable Healthcare Logistics, LLC

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.
Good afternoon Maria,

Below is the list of employees for each facility that you requested.

OH:

Jessenia Sanchez
Fred Dennis
Michael Bastian
David Haile
Micah Powers
Christopher Walker
Alontai Scott

NJ:

Carlos Chavez
Guadalupe Romero
Luis Diaz Gordillo
Eduard Gomez Rodriguez
Heriberto Lopez Gonzalez
Gerddy Mosquea
Vladimir Munoz Torres
Gerardo Ramos-Camacho
Mariela Peralta

Kind Regards,

Lizbeth Hernandes
Regulatory / Licensing Specialist
Reliable HealthCare Logistics, LLC
951 Clint Moore Road, Suite A
Boca Raton, FL 33487
(561) 998-3885 x216
lhernandes@reliablehealthcarelogistics.com
https://www.reliablehealthcarelogistics.com/

Reliable HealthCare Logistics

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
■ Ownership Change*	WH WH03468	■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)		☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Reliable HealthCare Logistics, LLC

Physical Address: 751 NW 33rd Street, Suite 190

City: Pompano Beach State: FL Zip: 33064

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Name of Designated Representative (DR): Cheryl Oleski

Licensing Company Email: 751LICENSE@RHCL3PL.COM DR Email: coleski@rhcl3pl.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Surgical Centers		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Trusted Partner Pharma Logistics, LLC

Corporation/Organization Name: Reliable HealthCare Logistics, LLC

Mailing Address: 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 216 Email: 751license@rhcl3pl.com

Contact Person Name: Lizbeth Hernandes

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Reliable HealthCare Logistics, LLC

Facility Name

Benjamin Maizel

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/28/21

Date

Board Use Only	Date Received: 11/4/25	Amount: $1000-ck 012892

An official website of the United States government Here's how you know

FDA

Drug Establishments Current Registration Site

New Search

Search Results for *Reliable HealthCare Logistics*

Showing 1 to 1 of 1 entry (filtered from 5 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Reliable Healthcare Logistics, LLC	3024552432	118841982	RELABEL; REPACK	751 NW 53RD St # 190, Pompano Beach, Florida (FL) 33064, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Tuesday, Aug 26, 2025

New Search

Verified
M.H 11/5/25

Reliable
HealthCare Logistics

Entity Organization Chart



Reliable HealthCare Logistics, LLC

List of Officers

Full Name: Benjamin Ephraim Maizel, as sole manager of Reliable HealthCare Logistics, LLC

Title: Chief Executive Officer

DOB [redacted]

Home Address: [redacted]

Business Address: 951 Clint Moore Road, Suite A, Boca Raton, FL 33487

Email Address: bmaizel@rhcl3pl.com

Phone Number: [redacted]

Reliable HealthCare Logistics, LLC

Reliable HealthCare Logistics, LLC provides Third Party Logistics (3PL) services specializing in supply chain solutions for the healthcare industry. Reliable HealthCare Logistics, LLC occupies a 44,053 square food industrial facility in Pompano Beach, FL.

Reliable HealthCare Logistics, LLC is maintained with a Controlled Room Temperature (CRT) of 68° F - 77°F and a secure environment that is properly license to meet FDA requirements.

Reliable HealthCare Logistics, LLC performs specific warehouse functions for receiving, storage, inventory management, order processing, fulfilment, transportation, and reporting. Reliable HealthCare Logistics, LLC stores and distributes Rx, Dietary supplements, Medical Device, and cosmetics.

Our Alarm System is with Johnson Controls Security Solutions which includes Burglar Alarm System, Access, Cards, and Video

Our Business Hours are 8:30 A.M. – 5:00 P.M. Monday – Friday.

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RELIABLE HEALTHCARE LOGISTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF AUGUST, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RELIABLE HEALTHCARE LOGISTICS, LLC" WAS FORMED ON THE FOURTH DAY OF MARCH, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6655021 8300

SR# 20252605244

Authentication: 203771864

Date: 08-23-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

CERTIFICATE OF FORMATION
OF
RELIABLE HEALTHCARE LOGISTICS, LLC

This Certificate of Formation of Reliable HealthCare Logistics, LLC is to be filed with the Secretary of State of the State of Delaware pursuant to Section 18-201 of the Delaware Limited Liability Company Act.

1. The name of the limited liability company is Reliable HealthCare Logistics, LLC.

2. The address of the limited liability company's registered office in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of the limited liability company's registered agent at such address shall be National Registered Agents, Inc.

Dated as of this 4th day of March, 2022.

/s/Rebecca Ware
Rebecca Ware, Authorized Person

32593134.1

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:35 PM 03/04/2022
FILED 01:35 PM 03/04/2022
SR 20220886439 - File Number 6655021

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Third Party Logistics Provider HEREIN HAS REGISTERED UNDER THE
PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

RELIABLE HEALTHCARE LOGISTICS LLC

RELIABLE HEALTHCARE LOGISTICS, LLC
751 NW 33RD STREET
SUITE 190
POMPANO BEACH FL 33064

LICENSE NUMBER: 02527

EXPIRATION DATE: DECEMBER 31, 2027

Always verify licenses online at MyFloridaLicense.com

ISSUED: 12/05/2025

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

KINSALE INSURANCE COMPANY
2035 Maywill Street, Suite 100
Richmond, VA 23230

DECLARATIONS - LIFE SCIENCES
GENERAL LIABILITY - CLAIMS MADE

Policy Number: 0100210519-3
Producer Number: 10014
Name and Address: RSG Specialty, LLC - Jupiter, FL (AR)
150 S. US Highway 1, 3rd Floor
Jupiter, FL 33477

NAMED INSURED:	Reliable Healthcare Logistics LLC
MAILING ADDRESS:	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
POLICY PERIOD:	FROM 10/11/2025 TO 05/12/2026 at 12:01 AM at the address of the named insured as shown above.

IN RETURN FOR THE PAYMENT OF THE PREMIUM, AND SUBJECT TO ALL THE TERMS OF THIS POLICY, WE AGREE WITH YOU TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

LIMITS OF INSURANCE		
Each Claim Limit	$1,000,000	Any one occurrence
Damage to Premises Rented to You Limit	$50,000	Any one premises
Personal and Advertising Injury Limit	$1,000,000	Any one person or organization
General Aggregate Limit	$2,000,000	
Products-Completed Operations Aggregate Limit	$2,000,000	

DEDUCTIBLE(S)	
Each Claim Deductible	$15,000

RETROACTIVE DATE

THIS INSURANCE DOES NOT APPLY TO "BODILY INJURY", "PROPERTY DAMAGE" OR "PERSONAL AND ADVERTISING INJURY" WHICH OCCURS BEFORE THE RETROACTIVE DATE, SHOWN BELOW.		
RETROACTIVE DATE (General Liability):	10/11/2022	at 12:01AM at the address of the named insured as shown above.

DESCRIPTION OF BUSINESS	
DESCRIPTION OF OPERATIONS:	**Pharmaceutical Distributor, Repackager, Relabeler**
BUSINESS TYPE:	Limited Liability Co

ALL PREMISES YOU OWN, RENT OR OCCUPY (If different than the mailing address)	
LOCATION	ADDRESS OF ALL PREMISES YOU OWN, RENT OR OCCUPY
1	1113 Gillingham Lane, Suite A, Sugar Land, TX 77478
2	751 NW 33rd St, Suite 190, Pompano Beach, FL 33064
3	5653 Creekside Pkwy, Lockbourne, OH 43137
4	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
5	6 Wheeling Rd, Dayton, NJ 08810

CLASSIFICATION AND PREMIUM					
CLASS CODE	CLASS DESCRIPTION	BASIS OF PREMIUM	EXPOSURE	RATE	PREMIUM
52343.02.21	Drug, Medicine or Pharmaceutical Preparations Mfg. - other than for animal use	per $1,000 Gross Sales	8,753,425	3.12	$27,298

TOTAL PREMIUM (DEPOSIT PREMIUM):	$27,298
COMPANY FEE:	$300
TOTAL PAYABLE AT INCEPTION:	**$27,598**

POLICY SUBJECT TO AUDIT:	Y	AUDIT PERIOD:	Annual

FORMS AND ENDORSEMENTS
Refer to ADF4001, SCHEDULE OF FORMS

THESE DECLARATIONS, TOGETHER WITH THE COMMON POLICY CONDITIONS AND COVERAGE FORM(S) AND ANY ENDORSEMENT(S), COMPLETE THE ABOVE NUMBERED POLICY.

PHILADELPHIA INSURANCE COMPANIES

Philadelphia Indemnity Insurance Company
One Bala Plaza, Ste. 100
Bala Cynwyd, PA 19004

BOND RIDER

Bond No: PB11499812250

Principal: RELIABLE HEALTHCARE LOGISTICS, LLC

Obligee: THE STATE OF NEVADA

Surety: Philadelphia Indemnity Insurance Company

Effective: August 30, 2025

It is agreed that: Adding Four Locations:

1. 751 NW 33rd Street, Suite 190, Pompano Beach, FL 33064
2. 6 Wheeling Road, Suite A, Dayton, NJ 08810
3. 5653 Creekside Parkway, Suite B, Lockbourne, OH 43137
4. 1113 Gillingham Lane, Suite A, Sugarland, TX 77478

Nothing herein contained shall be held to vary, waive, alter, or extend any of the terms, conditions, agreements or warranties of the above mentioned bond, other than stated as above. Provided, however, that the liability of the company under the attached bond as changed by this order shall not be cumulative.

Signed this 30th **day of** September **. 20** 25 **.**

Principal:

By: _____
Principal Signature

Philadelphia Indemnity Insurance Company

By: _____
John D. Weisbrot **Attorney in Fact**

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 30th day of September, 20 25

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
Mortgage loans	980,210	1,060,940
Real estate	45,943	21,033
Derivatives	3,552	-
Other invested assets (cost $219,302 and $201,673)	229,008	226,716
Receivables for securities sold	329	4,072
Cash, cash equivalents and short-term investments	176,533	147,539
Cash and invested assets	11,237,195	10,754,075
Premiums receivable, agents' balances and other receivables	1,166,132	1,108,771
Reinsurance recoverable on paid loss and loss adjustment expenses	63,067	57,589
Accrued investment income	94,377	93,350
Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 6,059,913	$ 5,797,285
Unearned premiums	1,990,597	1,887,004
Reinsurance payable on paid loss and loss adjustment expenses	39,877	35,204
Federal income taxes payable	-	2,352
Ceded reinsurance premiums payable	183,308	152,393
Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
Accrued expenses and other liabilities	54,505	62,438
Total liabilities	8,815,290	8,365,456
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 16, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11499812250

Application/License No. _____

RELIABLE HEALTHCARE LOGISTICS, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 951 CLINT MOORE ROAD, SUITE A, BOCA RATON, FL, 33487 (Address of Applicant/Principal), as PRINCIPAL, and Philadelphia Indemnity Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Bala Plaza, Suite 100 BALA CYNWYD PA 19004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Aug 30, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of September, 20 25.

APPLICANT/PRINCIPAL
RELIABLE HEALTHCARE LOGISTICS, LLC
COMPANY

Authorized Representative

SURETY
Philadelphia Indemnity Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

PHILADELPHIA INDEMNITY INSURANCE COMPANY CORPORATE SEAL 1927 PENNSYLVANIA

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**, that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 15th day of September, 2025.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

To verify the bond please visit https://www.suretybond.org/validate/?code=fVhD1U1Q4EaXhXA15TXkVADg&transaction=XFkG0VQV16cwheQwRcVVdJCQ

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
Mortgage loans	980,210	1,060,940
Real estate	45,943	21,033
Derivatives	3,552	-
Other invested assets (cost $219,302 and $201,673)	229,008	226,716
Receivables for securities sold	329	4,072
Cash, cash equivalents and short-term investments	176,533	147,539
Cash and invested assets	11,237,195	10,754,075
Premiums receivable, agents' balances and other receivables	1,166,132	1,108,771
Reinsurance recoverable on paid loss and loss adjustment expenses	63,067	57,589
Accrued investment income	94,377	93,350
Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 6,059,913	$ 5,797,285
Unearned premiums	1,990,597	1,887,004
Reinsurance payable on paid loss and loss adjustment expenses	39,877	35,204
Federal income taxes payable	-	2,352
Ceded reinsurance premiums payable	183,308	152,393
Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
Accrued expenses and other liabilities	54,505	62,438
Total liabilities	8,815,290	8,365,456
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Reliable HealthCare Logistics, LLC MDEG License # (if applicable) WH03468

Physical Address 751 NW 33rd Street, Suite 190

City Pompano Beach State FL Zip 33064

Mailing Address (if different from physical address) 951 Clint Moore Road, Suite A

City Boca Raton State FL Zip 33487

Telephone 561-998-3885 Ext 307 Website www.reliablehealthcarelogistics.com

Licensing Company Email 751LICENSE@RHCL3PL.COM

Section 2: Personal Information

First Cheryl Middle Ann Last Oleski

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Addres [redacted]

City West Palm Beach State FL Zip [redacted]

Telephone 561-998-3885 Ext 307 Email coleski@rhcl3pl.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Florida Atlantic University		09/78 - 12/89	
Address	City	State	Zip
777 Glades Road 201 Fleming Hall	Boca Raton	FL	33431
Diploma/Degree obtained, if any			
BA Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Broward Commnity College		0876 - 05/78	
Address	City	State	Zip
3501 Davie Rd	Davie	FL	33314
Diploma/Degree obtained, if any			
AA Medical Technology			

School Name		From - To (MM/YY – MM/YY)	
Saint Thomas Aquinas		09/72-05/76	
Address	City	State	Zip
2801 SW 12 St	Ft. Lauderdale	FL	33312
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2017 - Present	[redacted]	West Palm Beach	FL	[redacted]
2009 - 2017	[redacted]	Fort Lauderdale	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Reliable HealthCare Logistics, LLC			08/11//2022 - Present
Business Address	**City**	**State**	**Zip**
751 NW 33rd Street, Suite 190	Pompano Beach	FL	33064
Phone	**Title**	**Number of Employed Hours**	
561-998-3885 Ext 307	Director of Quality	6,704	

Description of Duties

Responsible for day-today quality operations for five Reliable HealthCare Logistics facilities. Hosts call regulatory and supplier audits and inspections

Business Name			From - To (MM/YY – MM/YY)
Acuderm, Inc.			02/2021-06/2022
Business Address	**City**	**State**	**Zip**
6555 Powerline Road	Ft. Lauderdale	FL	33309
Phone	**Title**	**Number of Employed Hours**	
954-733-6935	Quality Assurance Manager	2,773.33	

Description of Duties

Oversees daily operations of manufacturing groups to ensure compliance. See Attached Resume

Business Name			From - To (MM/YY – MM/YY)
Scientific Instruments, Inc.			02/2020 - 08/2020
Business Address	**City**	**State**	**Zip**
4400 Tiffany Drive	West Palm Beach	FL	33407
Phone	**Title**	**Number of Employed Hours**	
561-881-8500	Production Manager	1,040.00	

Description of Duties

Managed operations for four manufacturing groups. See Attached Resume

Business Name			From - To (MM/YY – MM/YY)
KRS Global Biotechnology, Inc.			01/2018- 05/2019
Business Address	**City**	**State**	**Zip**
791 Park of Commerce Blvd #600	Boca Raton	FL	33487
Phone	**Title**	**Number of Employed Hours**	
888-502-2050	Quality Assurance Manager and Corporate Trainer	2,773.33	

Description of Duties

Quality Assurance Manager responsible for all quality functions.

Business Name			From - To (MM/YY – MM/YY)
KRS Global Biotechnology, Inc.			08/2017 - 12/2017
Business Address	**City**	**State**	**Zip**
791 Park of Commerce Blvd #600	Boca Raton	FL	33487
Phone	**Title**	**Number of Employed Hours**	
888-502-2050	Quality Assurance Specialist	693.33	

Description of Duties

Quality duties, See Attached Resume

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
KRS Global Biotechnology, Inc.			11/2016 - 08/2017
Business Address		**City**	**State** / **Zip**
791 Park of Commerce Blvd #600		Boca Raton	FL / 33487
Phone	**Title**		**Number of Employed Hours**
888-502-2050	Production Supervisor		1,560.00
Description of Duties			
Supervision of Compounding Technicians for Sterile and Non-Sterile Production.			

Business Name			From - To (MM/YY – MM/YY)
Business Address		**City**	**State** / **Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address		**City**	**State** / **Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address		**City**	**State** / **Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address		**City**	**State** / **Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/30/2025
Date

I, Cheryl Ann Oleski, **certify that as the MDEG Administrator for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements):

1. C.O. Have a high school diploma or its equivalent;
2. C.O. Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. C.O. Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. C.O. Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cheryl Ann Oleski
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/30/2025
Date

Board Use Only	Date Received: 11/4/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Reliable HealthCare Logistics, LLC

Pharmacy/Wholesaler License # (if applicable): WH03468

Physical Address: 751 NW 33rd Street, Suite 190

City: Pompano Beach State: FL Zip: 33064

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 216 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: 751LICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Cheryl Middle: Ann Last: Oleski

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: West Palm Beach State: FL Zip: [redacted]

Telephone: 561-998-3885 Ext 307 Email: coleski@rhcl3pl.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Florida Atlantic University		09/78 - 12/89	
Address	**City**	**State**	**Zip**
777 Glades Road 201 Fleming Hall	Boca Raton	FL	33431
Diploma/Degree obtained, if any			
BA Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Broward Commnity College		0876 - 05/78	
Address	**City**	**State**	**Zip**
3501 Davie Rd	Davie	FL	33314
Diploma/Degree obtained, if any			
AA Medical Technology			

School Name		From - To (MM/YY – MM/YY)	
Saint Thomas Aquinas		09/72-05/76	
Address	**City**	**State**	**Zip**
2801 SW 12 St	Ft. Lauderdale	FL	33312
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2017 - Present	[redacted]	West Palm Beach	FL	[redacted]
2009 - 2017		Fort Lauderdale	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/11//2022 - Present	
Business Address		City	State	Zip
751 NW 33rd Street, Suite 190		Pompano Beach	FL	33064
Phone	Title		Number of Employed Hours	
561-998-3885 Ext 307	Director of Quality		6,704	
Description of Duties				
Responsible for day-today quality operations for five Reliable HealthCare Logistics facilities. Hosts call regulatory and supplier audits and inspections				

Business Name			From - To (MM/YY – MM/YY)	
Acuderm, Inc.			02/2021-06/2022	
Business Address		City	State	Zip
6555 Powerline Road		Ft. Lauderdale	FL	33309
Phone	Title		Number of Employed Hours	
954-733-6935	Quality Assurance Manager		2,773.33	
Description of Duties				
Oversees daily operations of manufacturing groups to ensure compliance. See Attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
Scientific Instruments, Inc.			02/2020 - 08/2020	
Business Address		City	State	Zip
4400 Tiffany Drive		West Palm Beach	FL	33407
Phone	Title		Number of Employed Hours	
561-881-8500	Production Manager		1,040.00	
Description of Duties				
Managed operations for four manufacturing groups. See Attached Resume				

Business Name			From - To (MM/YY – MM/YY)	
KRS Global Biotechnology, Inc.			01/2018- 05/2019	
Business Address		City	State	Zip
791 Park of Commerce Blvd #600		Boca Raton	FL	33487
Phone	Title		Number of Employed Hours	
888-502-2050	Quality Assurance Manager and Corporate Trainer		2,773.33	
Description of Duties				
Quality Assurance Manager responsible for all quality functions.				

Business Name			From - To (MM/YY – MM/YY)	
KRS Global Biotechnology, Inc.			08/2017 - 12/2017	
Business Address		City	State	Zip
791 Park of Commerce Blvd #600		Boca Raton	FL	33487
Phone	Title		Number of Employed Hours	
888-502-2050	Quality Assurance Specialist		693.33	
Description of Duties				
Quality duties, See Attached Resume				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
KRS Global Biotechnology, Inc.			11/2016 - 08/2017	
Business Address		City	State	Zip
791 Park of Commerce Blvd #600		Boca Raton	FL	33487
Phone	Title		Number of Employed Hours	
888-502-2050	Production Supervisor		1,560.00	
Description of Duties				
Supervision of Compounding Technicians for Sterile and Non-Sterile Production.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/30/2025
Date

I, Cheryl Oleski, **certify that as the designated representative for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. C.O. I am at least 21 years of age;
3. C.O. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. C.O. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. C.O. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. C.O. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. C.O. I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Cheryl Ann Oleski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/30/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cheryl Ann Oleski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/30/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach.

I, Cheryl Ann Oleski, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/30/2025

Date

Subscribed and Sworn to before me this 30th day of October, 2025.

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Reliable HealthCare Logistics, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03468

Physical Address: 751 NW 33rd Street, Suite 190

City: Pompano Beach State: FL Zip: 33064

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: 751LICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Benjamin Middle: Ephraim Last: Maizel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Dunedin State: FL Zip: [redacted]

Telephone: [redacted] Email: bmaizel@rhcl3pl.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fairleigh Dickenson University		1980-1983	
Address	**City**	**State**	**Zip**
1000 River Rd	Teaneck	NJ	07666
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Florida Gainesville		9/1975 - 6/1979	
Address	**City**	**State**	**Zip**
1478 Union Rd	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018 - Present	[redacted]	Dunedin	FL	[redacted]
2007-2018		Palm Harbor	FL	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fairleigh Dickenson University			
Address	**City**	**State**	**Zip**
1000 River Rd	Teaneck	NJ	07666
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Florida Gainesville			
Address	**City**	**State**	**Zip**
1478 Union Rd	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]	Dunedin	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Reliable HealthCare Logistics, LLC			08/01/2025 - Present
Business Address	**City**	**State**	**Zip**
951 Clint Moore Road, Suite A	Boca Raton	FL	33487
Phone	**Title**		
561-998-3885 Ext 207	CEO		

Description of Duties

CEO of Third-Party Logistics company, focused on the healthcare industry, specifically Generic Pharmaceutical companies.

Business Name			From - To (MM/YY – MM/YY)
Trusted Partner Pharma Logistics			01/2023 - Present
Business Address	**City**	**State**	**Zip**
3783 Winning Stakes Way	Mason	OH	45040
Phone	**Title**		
716-553-9641	CEO & Co-Founder		

Description of Duties

CEO & Co-Founder, Formed specific company to launch a generic focused 3PL

Business Name			From - To (MM/YY – MM/YY)
DiRx Inc			03/21 - 07/23
Business Address	**City**	**State**	**Zip**
2 TOWER CENTER Blvd Floor 12	East Brunswick	NJ	08816
Phone	**Title**		
(908) 356-0764	COO		

Description of Duties

Responsible for all aspects of physical pharmacy, product acquisition, pharmacy team including Customer Service, Outreach and Fulfillment teams, and Compliance.

Business Name			From - To (MM/YY – MM/YY)
McKesson			01/2018-03/2020
Business Address	**City**	**State**	**Zip**
	Mason	OH	
Phone	**Title**		
	Vice President		

Description of Duties

Completed Operational, Financial, Customer Service transition to RxCrossroads

Business Name			From - To (MM/YY – MM/YY)
RXTPL LLC			01/2012 - 12/2017
Business Address	**City**	**State**	**Zip**
	Mason	OH	
Phone	**Title**		
	President		

Description of Duties

CREATED a 3rd Party Logistics company for pharmaceutical manufacturers. Oversaw all aspects of the company, growing from zero to over 50 international manufacturers and growing business year over year

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Maizel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach.

I, Benjamin Maizel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/29/2025

Date

Subscribed and Sworn to before me this 29th day of October.

Hernandes

Notary Public Signature

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

(Seal)

Employee list for our 751 NW 33rd Street, Suite 190, Pompano Beach, FL 33064

Lucas, Danielle L	Pompano Beach, Florida
Rodriguez, Jose Manuel	Pompano Beach, Florida

IRS.gov

EIN Assistant

Your Progress: 1. Identity 2. Authenticate 3. Addresses 4. Details **5. EIN Confirmation**

Congratulations! Your EIN has been successfully assigned.

EIN Assigned: **85-1175079**

Legal Name: **RELIABLE HEALTHCARE LOGISTICS LLC**

IMPORTANT:

Save and/or print this page and the confirmation letter below for your permanent records.

The confirmation letter below is your official IRS notice and contains important information regarding your EIN.

CLICK HERE for Your EIN Confirmation Letter Help with saving and printing your letter

Once you have saved or printed your letter, click "Continue" to get additional information about using your new EIN. Continue >>

Help Topics

- What if I do not have access to a printer at this time?
- Can I access this letter at a later date?

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See *Specific Instructions* on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Reliable HealthCare Logistics, LLC

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☐ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☑ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) C

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions ☐

5 Address (number, street, and apt. or suite no.). See instructions.

951 Clint Moore Road, Suite A

Requester's name and address (optional)

6 City, state, and ZIP code

Boca Raton, FL 33487

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

8	8	–	1	1	7	5	0	7	9

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** [signature] **Date** 8-14-2025

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

Dated: July 03, 2025
The following is ORDERED:

Jennie D. Latta
UNITED STATES BANKRUPTCY JUDGE

UNITED STATES BANKRUPTCY COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

IN THE MATTER OF:

RELIABLE HEALTHCARE LOGISTICS, LLC	NO.: 24-20252-JDL
Debtor	CHAPTER 11

ORDER CONFIRMING PLAN OF REORGANIZATION FOR RELIABLE HEALTHCARE LOGISTICS, LLC BY TRUSTED PARTNER PHARMA LOGISTICS LLC AS COMPETING PLAN OF REORGANIZATION

Upon Trusted Partner Pharma Logistics, LLC filed a Competing Plan of Reorganization on April 3, 2025 (ECF No. 318), notice being sent to all creditors and parties in interest with plans and ballots of Reliable Healthcare Logistics, LLC ("Reliable") (ECF No. 321) the Court held confirmation hearing on June 26, 2025 based upon the Tally of Ballots for each competing Plan, objection filed by US Trustee; Limited Objection filed by Creditor Pool 5 Industrial TX, LLC ("Pool 5"); and the Limited Objection filed by BCI IV

Palm Beach CC LLC ("BCI IV") . At the hearing on these matters, the Court found the competing Plan of Reliable according to Tally of Ballots was not capable of confirmation and proceeded on the Tally of Ballots of TPPL and the cram down provisions of 11 U.S.C. Section 1129 for confirmation. After testimony of Benjamin Maziel, witness for TPPL on the elements for confirmation; argument and statements of counsel the Court found TPPL Plan confirmable as orally amended at the hearing and makes findings of fact and conclusions of law as follows:

1. The TPPL Plan complies with the applicable provisions of this title.
2. TPPL complies with applicable provisions of Title 11.
3. TPPL based on testimony of the witness has proposed the Plan in good faith and not by any means forbidden by law.
4. TPPL Plan and witness disclosed all the principals of reorganized company and all payments to be made or to be made acquiring property under the Plan, for services or for costs and expenses in or in connection with the case, or in connection with the Plan and incident to the case, has been approved by, or is subject to the approval of the court as reasonable.
5. TPPL by Plan and witness has disclosed the identity and affiliations of any individual proposed to serve, after confirmation of the plan, as a director, officer, or voting trustee of the debtor, an affiliate of the debtor participating in a joint plan with the debtor under the plan and such appointment to such office is consistent with the interests of creditors and public policy. There is no insider that will be employed or retained by the reorganized debtor.
6. With respect to each impaired class of claims or interest the impaired class has

accepted the TPPL Plan or will receive or retain under the plan on account of such claim or interest property of a value, as of the effective date of the plan, that is not less than the amount that such holder would so receive or retain if the debtor were liquidated under Chapter 7 of this title on such date.

7. Class 3.04 Pre-Petition Unsecured Claim of BCI IV treatment is amended to provide as follows:

Class 3.04 consists of the allowed unsecured claim due to BCI IV Palm Beach, LLC ("BCI") for prepetition rent arrearages in the amount of $550,915.57 (the "Cure Amount") for the lease of non-residential real property located at 951 Clint Moore Road, Boca Raton, Florida (the "Lease"). Upon the Effective Date, the Lease shall be assumed by the Debtor. BCI shall retain its pre-petition security deposit as security for the lease. Upon the Effective Date, BCI shall have an allowed unsecured claim for the Cure Amount and the Debtor shall pay thirty percent (30%) of the Cure Amount. The balance of the Cure Amount shall be paid in 9 equal monthly installments commencing thirty days following the initial payment. Upon written notice from BCI of any default by the Debtor in the payment of the Cure Amount, the Debtor shall have ten (10) days to cure such default. Any defaults with respect to the payment of ongoing rent payments shall be governed by the terms of the Lease.

8. Class 4.04 Pre-Petition Unsecured Claims of Certain Lawsuits is amended to specify in the Encube litigation that the Reorganized Debtor will dismiss the Delaware litigation against Encube with prejudice and Encube will not receive any distribution on its claim against the Debtor; that the Debtor's objection to

Encube's claim is deemed compromised and settled and by this amendment Encube accepts the Plan and all costs associated with such litigation will be paid by each party for their own fees and expenses.

9. Class 5 Interests of Reliable Healthcare Logistics Investments, LLC, pre-petition sole membership interest in the Debtor, is extinguished on the Effective Date. TPPL is contributing new capital to the reorganized debtor in the amount of $500,000 in exchange for one hundred percent (100%) of the membership interest in the reorganized Debtor. The Reorganized Debtor continues to be the same legal entity upon confirmation. The new capital will be paid on or before the Effective Date in full. Class 5

10. All property comprising of the Estate (including causes of action, but excluding property that has been abandoned pursuant to an order of the Bankruptcy Court) shall vest in the Reorganized Debtor, as of the Effective Date, free and clear of all Claims, liens, charges, encumbrances, rights and Interests of creditors and equity security holders. As of the Effective Date, the Reorganized Debtor may operate its business and use, acquire, and dispose of property and settle and compromise Claims or Interests without supervision of the Bankruptcy Court, free of any restrictions of the Bankruptcy Code or Bankruptcy Rules, other than those restrictions expressly imposed by this Plan and Confirmation Order. Except as otherwise provided in any provision of the Plan, upon entry of the Order of Confirmation and pursuant to 11 U.S.C. § 1141(b) and (c), any and all property of the Estate shall vest in the reorganized Debtor free of all liens, security interests, mortgages or other interests in property secured by an Allowed Claim except as

expressly provided for in the Plan. Pursuant to §1146(c), no stamp taxes, transfer tax or Tennessee indebtedness tax or other similar taxes shall be due as a result of the making or delivery of an instrument of transfer pursuant to the Plan.

11. Paragraph K.(4) on Exculpation and Limitation of Liability of TPPL Plan is hereby deleted in full upon objection of US Trustee.

12. Pursuant to this Court's order of March 31, 2025, the proof of claim of Pool 5 Industrial TX, LLC is disallowed. Pool 5 has appealed the Court's order. In the event Pool 5's claim becomes an allowed administrative expense claim or allowed unsecured claim, then such claim shall be deemed incorporated into the Plan with the same priority and classification as such other similarly situated administrative expense claims (Class 1) and/or pre-petition unsecured claims related to rejected/terminated leases (Class 4.01).

13. The Plan will become effective on or before the first business day following fourteen (14) days after the Confirmation Order becomes a Final Order. Upon Final Order the Reorganized Debtor will have full access to all accounts, books and records of Reliable.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED THAT the objections to Plan are denied and the Court makes findings of fact and conclusions of law in regard to the Plan and confirmation as stated above. There is at least one accepting impaired class voting for Plan of TPPL. The TPPL Plan is confirmed based upon the testimony of the witness and amendments as stated herein.

Approved

/s/ Toni Campbell Parker

TONI CAMPBELL PARKER (TN # 6984)
ATTORNEY FOR TPPL
45 North BB King Blvd,. SUITE 201
MEMPHIS, TENNESSEE 38103
Tparker002@att,net
(901) 483-1020

/s /s/ Carrie Ann Rohrscheib,
Carrie Ann Rohrscheib
Attorney for US Trustee

/s/ R. Campbell Hillyer
R. Campbell Hillyer
Attorney for BCI IV Plam Beach CC LLC and Pool 5D

/s/ David W. Houston IV
David W. Houston IV
Attorney for Encube

/s/ Michael P. Coury
Michael P. Coury
Attorney for Reliable Healthcare Logistics, LLC

CC

Debtpr:

Office of US Trustee
All creditors of this estate and all parties on the mailing matrix of Debtor

4904-7001-6082, v. 1

Reliable HealthCare Logistics, LLC

License List

RHL Facility	State	License Number	License Type	License Issue Date	License Expiration Date
751 Pompano	Alabama	196451	Third-Party Logistics Provider	9/8/2023	12/31/2025
751 Pompano	Alaska	202090	Third-Party Logistics Provider	11/8/2022	6/30/2026
751 Pompano	Arkansas	WD05784	Wholesale Distributor License	12/6/2022	12/31/2026
751 Pompano	Colorado	TPLP.0000056	Third Party Logistics Provider	4/12/2023	10/31/2026
751 Pompano	Connecticut	CSW.0005190	Wholesaler of Drugs, Cosmetics & Medical Devices	7/1/2023	6/30/2026
751 Pompano	Delaware	A4-0013168	Pharmacy - Wholesale	5/1/2023	9/30/2026
751 Pompano	Florida	TEMP508	Temporary - Third Party Logistics Provider Permit	8/29/2025	11/26/2025
751 Pompano	Georgia	PHWH005555	Wholesaler Pharmacy	4/21/2023	6/30/2027
751 Pompano	Illinois	278.000196	Wholesaler Drug Third Party Logistics Provider	4/18/2024	12/31/2026
751 Pompano	Indiana	94000330A	Third Party Logistics Provider	9/19/2025	9/30/2026
751 Pompano	Kansas	23-126189	Third Party Logistics Provider	9/12/2025	6/30/2026
751 Pompano	Kentucky	TPL00510	Third Party Logistic	8/25/2025	6/30/2026
751 Pompano	Louisiana	11719	Distributor of Legend Drugs or Legend Devices	9/10/2025	12/31/2025
751 Pompano	Maine	WH70003503	Pharmaceutical Wholesaler	4/12/2023	12/31/2025
751 Pompano	Maryland	D07284	Distributor	5/1/2023	5/31/2027
751 Pompano	Michigan	5306007343	Wholesale Distributor	8/16/2023	8/16/2027
751 Pompano	Minnesota	900288	Third Party Logistics Provider	9/22/2025	10/31/2026
751 Pompano	Mississippi	18638/16.3a	Drug Facility - 3rd Party Logistics (Non-Resident)	3/7/2023	12/31/2025
751 Pompano	Missouri	2025042633	Third-Party Logistics Provider	9/29/2025	10/31/2027
751 Pompano	Montana	PHA-WDD-LIC-117720	Wholesale Drug Distributor License	3/2/2023	11/30/2025
751 Pompano	Nevada	WH03468	Wholesaler	7/14/2023	10/31/2026
751 Pompano	New Hampshire	08385	Man/Dist/Whole/Broker	1/17/2023	8/29/2027
751 Pompano	New Mexico	WD20220401	Temporary - Third Party Logistics Provider Permit	9/3/2025	12/31/2027
751 Pompano	North Carolina	1697	Third Party Logistics Provider	1/6/2023	12/31/2025
751 Pompano	Ohio	0170000108	Third Party Logistics - Category 2	2/8/2023	6/30/2027
751 Pompano	Oklahoma	88-L-9230	3PL Provider	9/12/2025	9/30/2026
751 Pompano	Oregon	DDA-0000633	Drug Distribution Agent	3/13/2023	9/30/2026
751 Pompano	Pennsylvania	3000010485	Distributor of Prescription Drugs	3/5/2023	3/31/2026
751 Pompano	Rhode Island	DIS04021	Drug Wholesaler - Out of State	2/20/2023	9/30/2026
751 Pompano	South Carolina	23422	Non-Resident Third Party Logistics Provider	8/26/2025	6/30/2026
751 Pompano	Tennessee	8452	Third Party Logistics	12/22/2022	7/31/2026
751 Pompano	Texas	1003585	Rx Out of State - Wholesale Distributor	3/3/2023	1/11/2027
751 Pompano	Utah	14243284-1714	Pharmacy - Class E Business	9/8/2025	9/30/2027
751 Pompano	West Virginia	3PL0000499	Third Party Logistics Provider	8/29/2025	6/30/2026
751 Pompano	Wisconin	10046-45	Wholesale Distributor of Prescription Drugs	9/21/2023	5/31/2026

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ENTRY NOTICE AND ON-SITE INSPECTION REPORT

DBA Name:	RELIABLE HEALTHCARE LOGISTICS, LLC	Form Date:	Oct 29, 2025 08:49
Full Legal Name:	RELIABLE HEALTHCARE LOGISTICS LLC	Permit Number:	Rank:
Inspection Reason:	New Bus -X	Telephone Number:	5619983885
Address:	751 NW 33RD STREET, SUITE 190 POMPANO BEACH FL 33064	Inspection Visit ID:	13545776
		File Number:	674
		Permit Type:	3302

INSPECTION RESULT Completed

Inspection Authority 499.051 F.S., 61N-1.019, F.A.C. (03/10/2017)

Person Receiving Report/Title Lizbeth Hernandes, Regulatory/Licensing Specialist

Facility Hours 61N-1.015(2)(c), F.A.C.

Hours	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30AM	8:30AM	8:30AM	8:30AM	8:30AM	Closed	Closed
Close	5PM	5PM	5PM	5PM	5PM		

FACILITY/STORAGE [(Rx drug establishments) FS 499.01(2) and 499.0121(1)(b),(d),(e)]

1. Is the establishment a residence? [F.S. 499.012(1)(b)]	No	
2. Lighting adequate? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.44] [(Cosmetic manufacturers) 61N-1.010(2)(e), F.A.C.]	Yes	
3. Pest Free? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.56] [(Cosmetic manufacturers) 61N-1.010(2)(b), F.A.C.]	Yes	
4. Clean and orderly? [(OTC drug manufacturers) 61N-1.014(4), F.A.C.] [(Cosmetic manufacturers) 61N-1.010(2)(a), F.A.C.]	Yes	

RECORD KEEPING [F.S. 499.0121(6)] [61N-1.012 F.A.C.]

5. All records computer based?	No	Electronic and manually
6. Location of hard copy?		In a lock file cabinet inside of the Logistics manager office
7. All records manual?	No	
8. On-site storage?	Yes	
9. Shares facility?	No	
10. If yes to #9, separate records?	N/E	N/A

PRESCRIPTION DRUG ESTABLISHMENT

11. Is the name identical to another person authorized to purchase legend drugs? [F.S. 499.012(1)(c)] [61N-1.015(2)(b), F.A.C.]	Yes	Have multiple location (locations) see notes
12. Is the person a broker only as defined under [61N-1.001(2)(d), F.A.C.]?	No	

SECURITY [(Rx drug establishments) FS 499.0121(2)(a), (b) and 499.0121(10)(b) or 61N-1.013(1), F.A.C.]

13. Access restricted? [(OTC drug manufacturers) FS 499.01(2)(n)3 and 21 CFR 211.28(c)] [(Cosmetic manufacturers) 61N-1.010(4)(f), F.A.C.]	Yes	
14. Drug facility alarmed?	Yes	Johnson Control security

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15. Telephone monitoring?	N/E	
16. Controlled substance cage (CIII-CV)? [21 CFR 1301.72]	N/E	New permit inspection, will not have controlled substances
17. Controlled Substance CII vault? [21 CFR 1301.72]	N/E	New permit inspection, will not have controlled substances

STORAGE [(Rx drug establishments) FS 499.0121(3)(5) or 61N-1.013(3)(4), F.A.C.] [(OTC drug manufacturers) 61N-1.014, F.A.C., and/or FS 499.01(2)(n)3 and 21 CFR 211.46] [(Cosmetic manufacturers) 61N-1.010(2), F.A.C.]

18. Quarantine area?	Yes	
19. Air conditioner?	Yes	
20. Method of monitoring?		Dickson Sytem
21. Refrigeration present?	N/E	N/A
22. Handles drugs or cosmetics requiring refrigeration?		New inspection
23. Method of monitoring refrigeration?		New inspection
24. Freezer present?	N/E	N/A
25. Handles drugs or cosmetics requiring freezing?	N/E	N/A
26. Method of monitoring freezing temperatures?		N/A

WRITTEN POLICIES AND PROCEDURES [(Rx drug establishments and OTC manufacturers) FS 499.0121(6)(8)(10), 499.01(2) and/or 21 CFR Part 211] [(Cosmetic manufactures) 61N-1.010, F.A.C.]

27. Exist?	Yes	
28. Rx drug annual examination? [F.S. 499.0121(5)(a)2]	Yes	
29. Drug FIFO inventory?	Yes	
30. Recalls/emergencies?	Yes	
31. Natural disasters for Rx drug establishments?	Yes	
32. Receipt and distribution business records?	Yes	
33. Transaction Information, History and Statement (T3) for Rx drug products?	N/E	3PL Providers do not own the products. See noes

INBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Purchases and/or Receipts) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]

34. What are firm's all-inclusive inbound business records that it receives from its Rx drug source(s) per firm for this establishment?	Will obtain ASN, COA, packing list,

OUTBOUND PRESCRIPTION DRUG BUSINESS RECORDS (Sales or Otherwise) [FS 499.0121(6)(b)] [61N-1.012(1)(a),(2)(a), F.A.C.]

35. What are firm's all-inclusive typical outbound business records (e.g., sales invoice, packing list, etc.) that it provides to the purchaser and recipient for each Rx drug distribution from this establishment according to firm?		Will provide BOL and order, using their DATEX system
36a. Did firm provide its all-inclusive outbound business records for one (1) of its typical Rx drug distribution?	N/E	New permit inspection so there are no records for operations under this permit yet
36b. If yes to 36a, what is the tracking number (e.g., sales invoice or order number, etc.) and distribution date for this provided distribution document?		New permit inspection so there are no records for operations under this permit yet
37. Of the document(s) provided in 36a, which document contains the minimum required recordkeeping business elements according to firm?		New permit inspection so there are no records for operations under this permit yet

38. For the document type referenced in 37 regarding this establishment's outbound Rx drug distributions:

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38a. Did firm mark "A" next to the field that lists the seller's name and address?	N/E	New permit inspection
38b. Did firm mark "B" next to the field that lists the seller's Florida permit number?	N/E	New permit inspection
38c. Did firm mark "C" next to the field that lists the shipper's name and address when different from the seller?	N/E	New permit inspection
38d. Did firm mark "D" next to the field that lists the distribution date?	N/E	New permit inspection
38e. Did firm mark "E" next to the field that lists the name, strength, dosage form, quantity, and (when assigned) the National Drug Code (NDC) of the Rx drug?	N/E	New permit inspection
38f. Did firm mark "F" next to the field that lists the financial data?	N/E	New permit inspection
38g. Did firm mark "G" next to the field that lists the purchaser's name, address, and Florida permit number?	N/E	New permit inspection
38h. Did firm mark "H" next to the field that lists the physical recipient's name, address and permit or license number, when the recipient is different from the purchaser?	N/E	New permit inspection

N/E = Not Evaluated

Inspection Notes

Inspection Notes

Reliable Healthcare Logistics LLC
751 NW 33rd Street, Suite190,
Pompano Beach, FL 33064
Permit type: 3302
File Number: 674
Application Number: 3230

Inspection is for a new Third-Party Logistics permit.

This inspection was conducted on October 29, 2025. Inspector Specialist Ariesa Render entered the facility at 10AM and presented credentials.

For the purposes of this inspection report Reliable Healthcare Logistics LLC will be referred to by name or as the Firm. Unless specifically indicated by name Cheryl Oleski (Director of Quality), Marisa Jonhson (Documentation Specialist), Danielle Lucas (Logistics Manager) answered questions and provided documents during this inspection and will be referred to by name or collectively as the Firm.

What are the Firm's Hours of operation? 8:30 A.M. – 5:00 P.M. Monday - Friday

Is Firm a closely held corporation or LLC? Limited Liability Company

• Please list firm owners and percentage ownership. Trusted Partner Pharma Logistics, LLC at 100%

• What is firm's website address, if applicable? www.reliablehealthcarelogistics.com

List of the key employees and titles:
• Benjamin Maizel – Chief Executive Officer

- Cheryl Oleski – Director of Quality
- Danielle Lucas – Logistics Manager
- Krysta Sinisgalli – Director of Operations
- Lizbeth Hernandes – Regulatory Licensing Specialist

How many full-time employees, part-time employees and Seasonal employees does firm have? 3 full time.

Reliable Healthcare Logistics LLC Locations:

1. 951 Clint Moore Rd. Suite A, Boca Raton, FL 33487
2. 751 NW 33rd St, Suite 190, Pompano Beach, FL 33064
3. 1113 Gillingham Ln A, Sugar Land, TX 77478
4. 6 Wheeling Rd Suite A, Dayton, NJ 08810
5. 5653 Creekside Pkwy Suite B, Lockbourne, OH 43137

Facility
1. What is the total square footage of the facility? 44,053 square feet
2. Does firm share facilities with other firms? No
3. Please provide names of firms, permit numbers and types of operations if applicable. Reliable HealthCare Logistics, LLC – TEMP508
4. How long has firm been in its current location? Since August 2022
5. Is this facility leased or owned? leased
6. Does Firm have its local city and county business tax receipt? Yes
7. Are all permits clearly posted? Yes
8. Does Firm have an alarm system? if so, name of the company. Yes, with Johnson Control Security. The Firm has eight cameras that are monitored in-house.
9. What does the alarm system consist of? Burglar Alarm System, Access Cards, and video
10. Is there a 24-hour telephone monitored alarm system, motion detectors and surveillance cameras? Yes
11. Is the facility monitored 24/7? yes
12. How many motion detectors and cameras are there? 5
13. If there is a breach, who is alerted? The firm will follow their SOP-WH-007(REV 02). Disaster Preparedness and Recovery Plan and the accompanying form F-WH-007-A (REV 05)
14. Is the warehouse secure? yes
15. Who will have access to the warehouse where RX drugs are stored? Logistics Manager, Designated Representative, Director of Operations. Account Coordinators and Warehouse Staff trained to pick and pack orders.
16. Does the facility have adequate lighting? yes
17. Does Firm have any off –site locations that is used for warehouse storage of RX drugs? Yes, 951 Clint Moore Road, Suite A, Boca Raton, FL 33487 – License # TEMP509
18. Is Firm registered with FDA? yes
19. Does Firm hold licenses in any other states? Yes
20. Does Firm have any other permits with the FL DBPR? Not for this location.

Please describe firm's all-inclusive business activities in detail.

21. What business activities does firm intend on conducting once Third-Party logistics permit is obtained? The activities will be storage, fulfillment, and distribution of Rx, OTC, and Dietary Supplements
22. Please list Firm's intended customers. OTC, Cosmetics, RX products (drug and device)
23. How often does Firm conduct a physical inventory? Inventories are requested by Product owners. WMS is used to verify inventory systematically and physical counts are conducted and verified by staff. Cycle counts can be requested and performed by Warehouse and Operations staff members.
24. How will Firm handle the return and/or destruction of unwanted, expired, or otherwise unusable raw materials and finished

products? Product will not be returned to this location.

Explain business records.

25. What will Inbound business records include (for example: packing slip and invoice etc.) ASN, COA, Packing list. The T3 information will be obtain by the firm at the time the inbound products are scanned.
26. What will Outbound business records include: (For example invoices etc.) BOL, and order form
27. How will Firm provide documents to the manufacturer or wholesaler they are contracted with? Electronically.
28. How will firm provide documents to their customers? Clients have access to their live inventory whenever they log into their client portal.
29. How will records be kept? Electronically, Manually or both? both
30. How will the firm back up records? Electronically system is back-up every evening into the cloud.
31. How many years will records be stored? Per SOP-WH-002 – Three years
32. Does Firm have a copy of Chapter 499 Florida Statutes and Chapter 61N-1 FAC at the establishment? Where is it stored (Physically or electronically)? Yes, Electronically

Pest control

33. What pest control service does firm use? Florida Pest Control
34. What does pest control consist of: ILT (Insect light traps) that use LED or UV lighting to attract insects to a sticky glue board. These are located near bay doors and pedestrian doors, rodent traps (tincat style) which physically trap rodents without the use of poison. These are located inside the warehouse. Outdoor rodent bait stations that have poison bait placed. Pesticide spray applied in offices, kitchen and bathrooms
35. How often does firm receive pest control services? Monthly

Storage of drugs:

36. Where will Firm's RX drugs be stored? Will there be restricted access? It will be kept in the warehouse. Yes, access is restricted.
37. Is there a distinct area for prescription drugs? Yes

Temperature and Humidity.

38. How will Firm monitor temperature and humidity? They will use Dickson system.
39. Will a Refrigerator/Freezer be utilized? No

Destruction/ Reverse distribution:

40. Does firm have reverse distribution or destruction services? Not at this location
41. Does Firm plan to export prescription drugs? No

Tour conducted at 10:08AM revealed the warehouse was very spacious. The Firm has designated quarantine areas. Observation of the warehouse area revealed there was adequate lighting. The facility is heavily secured and monitored. Products were off the floor. Further observation revealed the walls and floors were clean and smooth.

The Firm is aware of the following:

- Any changes to the application must be reported to Tallahassee. {499.012}
- A permit issued by DBPR is non-transferable, any changes made to the application must be reported to Tallahassee in writing before the effective date of the change {499.012}
- Business records must be kept separate and distinct from other businesses conducted at this facility {61N-1.012(12)}

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• The Firm must be available for inspection by the Department during business hours. The Firm may not refuse inspection by the Department, including photographs and the review and copying of any record. {499.051 F.S., 61N-1.015(2)(c) F.A.C and 61N-1.019 F.A.C.}
• Business records must be maintained for a period of not less than 6 years. {499.012(6)(f) F.S.
• To review F.S. Chapter 499 Part I and Chapters 61N-1 and 61N-2, F.A.C. for the requirements for permit type.

A copy of the report was provided by email to Lizbeth Hernandes lhernandes@reliablehealthcarelogistics.com

Additional information related to this inspection may be requested from the Firm following the on-site inspection, if necessary. Statues and rule citations have been included in this report for Firms convenience and reference but should not be considered as an all-inclusive representation of applicable regulations.

Please refer to Chapter 499 Florida Statues and Rule 61N-1 Florida Administrative code. A link to the statues and rules can be found on the division's website www.myfloridalicense.com/dpbr/ddc

Licensee Not Present to Sign

Licensee or Owner Signature

Lizbeth Hernandes
Regulatory / Licensing Specialists
951 Clint Moore Road, Suite A
Boca Raton, FL 33487
561-998-3885
Oct 30, 2025 11:04

Inspector Signature

Aniesa Render
Inspection Specialist
1525 West Cypress Creek Rd
Fort Lauderdale, FL 33301
Aniesa.Render@myfloridalicense.com
850-251-0021
Oct 30, 2025 11:04

October 30, 2025 at 11:04:31 AM EDT
Location: RELIABLE HEALTHCARE LOGISTICS, LLC
License #:
Inspector: Aniesa Render

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH WH03466	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Reliable HealthCare Logistics, LLC

Physical Address: 1113 Gillingham Lane, Suite A

City: Sugarland State: TX Zip: 77478

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Name of Designated Representative (DR): Christopher Martin

Licensing Company Email: sugarlandlicense@rhcl3pl.com DR Email: cmartin@rhcl3pl.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ■ Veterinarians ■ Others: Surgical Centers	■ Dangerous Drugs ☐ Controlled Substances ■ *Medical devices, equipment, supplies, gases ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ■ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Trusted Partner Pharma Logistics, LLC

Corporation/Organization Name: Reliable HealthCare Logistics, LLC

Mailing Address: 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 216 Email: NJlicense@rhcl3pl.com

Contact Person Name: Lizbeth Hernandes

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Reliable HealthCare Logistics, LLC

Facility Name

Benjamin Maizel

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/23/25

Date

Board Use Only	Date Received: 11/4/25	Amount: $1000 Check 012656

An official website of the United States government Here's how you know

FDA

Share Tweet Linkedin Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Reliable HealthCare Logistics*

Showing 1 to 1 of 1 entries (filtered from 5 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Reliable Healthcare Logistics, LLC	3024548814	118890247	RELABEL; REPACK	1113 Gillingham Ln Ste A, Sugar Land, Texas (TX) 77478, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Tuesday, Dec 10, 2024

New Search

Verified MH 11/5/25

Reliable HealthCare Logistics, LLC

List of Officers

Full Name: Benjamin Ephraim Maizel, as sole manager of Reliable HealthCare Logistics, LLC

Title: Chief Executive Officer

DOB: [redacted]

Home Address [redacted]

Business Address: 951 Clint Moore Road, Suite A, Boca Raton, FL 33487

Email Address: bmaizel@rhcl3pl.com

Phone Number [redacted]

Reliable HealthCare Logistics, LLC

Reliable HealthCare Logistics, LLC provides Third Party Logistics (3PL) services specializing in supply chain solutions for the healthcare industry. Reliable HealthCare Logistics, LLC occupies a 50,525 square foot industrial facility in Sugarland TX.

Reliable HealthCare Logistics, LLC is maintained with a Controlled Room Temperature (CRT) of 68° F - 77°F and a secure environment that is properly license to meet FDA requirements.

Reliable HealthCare Logistics, LLC performs specific warehouse functions for receiving, storage, inventory management, order processing, fulfilment, transportation, and reporting. Reliable HealthCare Logistics, LLC stores and distributes Rx, Dietary supplements, Medical Device, and cosmetics.

Our Alarm System is with Johnson Controls Security Solutions which includes Burglar Alarm System, Access, Cards, and Video

Our Business Hours are 8:30 A.M. – 5:00 P.M. Monday – Friday.

Reliable HealthCare Logistics

Entity Organization Chart



Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RELIABLE HEALTHCARE LOGISTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF AUGUST, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RELIABLE HEALTHCARE LOGISTICS, LLC" WAS FORMED ON THE FOURTH DAY OF MARCH, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203771864

Date: 08-23-25

6655021 8300

SR# 20252605244

You may verify this certificate online at corp.delaware.gov/authver.shtml

CERTIFICATE OF FORMATION
OF
RELIABLE HEALTHCARE LOGISTICS, LLC

This Certificate of Formation of Reliable HealthCare Logistics, LLC is to be filed with the Secretary of State of the State of Delaware pursuant to Section 18-201 of the Delaware Limited Liability Company Act.

1. The name of the limited liability company is Reliable HealthCare Logistics, LLC.

2. The address of the limited liability company's registered office in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of the limited liability company's registered agent at such address shall be National Registered Agents, Inc.

Dated as of this 4th day of March, 2022.

/s/Rebecca Ware
Rebecca Ware, Authorized Person

32593134.1

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:35 PM 03/04/2022
FILED 01:35 PM 03/04/2022
SR 20220886439 - File Number 6655021

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/drug-manufacturers-distributors/applications-forms-drug-manufacturers-distributor**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

RELIABLE HEALTHCARE LOGISTICS LLC
951 CLINT MOORE RD STE A
BOCA RATON FL 33487

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

RELIABLE HEALTHCARE LOGISTICS LLC

1113 GILLINGHAM LN STE A
SUGAR LAND, TX 77478

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003550
Expires: August 22, 2026

NON-TRANSFERABLE

Commissioner

518637

TEXAS
Health and Human Services

Texas Department of State Health Services

Jennifer A. Shuford, M.D., M.P.H.
Commissioner

October 14, 2025

Lizbeth Hernandes
Reliable HealthCare Logistics LLC
lhernandes@reliablehealthcarelogistics.com

CFN: 2108777
Lic.: 1003550
Type: 2501
File: 6720

Re: License Verification

Dear Lizbeth Hernandes:

This letter shall serve as a verification of licensure for the following firm:
RELIABLE HEALTHCARE LOGISTICS LLC
1113 GILLINGHAM LN STE A
SUGAR LAND, TX 77478

License No.	1003550
Type of license:	Prescription Drug Distributor, 3PL
Status of license:	Current
Date license issued:	08/06/2024
Date license expires:	08/22/2026
Disciplinary action:	None

The firm is in good standing as of the date of this letter.

If you have questions or need additional information, please contact me at 512-834-4503, via fax at (512) 834-6759, or email me at Justin.Arnold@dshs.texas.gov.

Sincerely,

Justin Arnold, MBA, RS
Medical Research Specialist
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Justin Arnold
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/drug-manufacturers-distributors/applications-forms-drug-manufacturers-distributor**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

RELIABLE HEALTHCARE LOGISTICS LLC
951 CLINT MOORE RD STE A
BOCA RATON FL 33487

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

RELIABLE HEALTHCARE LOGISTICS LLC

1113 GILLINGHAM LN STE A
SUGAR LAND, TX 77478

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WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003550
Expires: August 22, 2026

NON-TRANSFERABLE

Commissioner

518637

KINSALE INSURANCE COMPANY
2035 Maywill Street, Suite 100
Richmond, VA 23230

DECLARATIONS - LIFE SCIENCES
GENERAL LIABILITY - CLAIMS MADE

Policy Number: 0100210519-3
Producer Number: 10014
Name and Address: RSG Specialty, LLC - Jupiter, FL (AR)
150 S. US Highway 1, 3rd Floor
Jupiter, FL 33477

NAMED INSURED:	**Reliable Healthcare Logistics LLC**
MAILING ADDRESS:	**951 Clint Moore Road, Suite A, Boca Raton, FL 33487**
POLICY PERIOD:	**FROM 10/11/2025 TO 05/12/2026 at 12:01 AM at the address of the named insured as shown above.**

IN RETURN FOR THE PAYMENT OF THE PREMIUM, AND SUBJECT TO ALL THE TERMS OF THIS POLICY, WE AGREE WITH YOU TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

LIMITS OF INSURANCE		
Each Claim Limit	$1,000,000	Any one occurrence
Damage to Premises Rented to You Limit	$50,000	Any one premises
Personal and Advertising Injury Limit	$1,000,000	Any one person or organization
General Aggregate Limit	$2,000,000	
Products-Completed Operations Aggregate Limit	$2,000,000	

DEDUCTIBLE(S)	
Each Claim Deductible	$15,000

RETROACTIVE DATE

THIS INSURANCE DOES NOT APPLY TO "BODILY INJURY", "PROPERTY DAMAGE" OR "PERSONAL AND ADVERTISING INJURY" WHICH OCCURS BEFORE THE RETROACTIVE DATE, SHOWN BELOW.		
RETROACTIVE DATE (General Liability):	10/11/2022	at 12:01AM at the address of the named insured as shown above.

DESCRIPTION OF BUSINESS	
DESCRIPTION OF OPERATIONS:	**Pharmaceutical Distributor, Repackager, Relabeler**
BUSINESS TYPE:	Limited Liability Co

ALL PREMISES YOU OWN, RENT OR OCCUPY (if different than the mailing address)	
LOCATION	ADDRESS OF ALL PREMISES YOU OWN, RENT OR OCCUPY
1	1113 Gillingham Lane, Suite A, Sugar Land, TX 77478
2	751 NW 33rd St, Suite 190, Pompano Beach, FL 33064
3	5653 Creekside Pkwy, Lockbourne, OH 43137
4	951 Clint Moore Road, Suite A, Boca Raton, FL 33487
5	6 Wheeling Rd, Dayton, NJ 08810

CLASSIFICATION AND PREMIUM					
CLASS CODE	CLASS DESCRIPTION	BASIS OF PREMIUM	EXPOSURE	RATE	PREMIUM
52343.02.21	Drug, Medicine or Pharmaceutical Preparations Mfg. - other than for animal use	per $1,000 Gross Sales	8,753,425	3.12	$27,298

TOTAL PREMIUM (DEPOSIT PREMIUM):	$27,298
COMPANY FEE:	$300
TOTAL PAYABLE AT INCEPTION:	**$27,598**

POLICY SUBJECT TO AUDIT:	Y	AUDIT PERIOD:	Annual

FORMS AND ENDORSEMENTS
Refer to ADF4001, SCHEDULE OF FORMS

THESE DECLARATIONS, TOGETHER WITH THE COMMON POLICY CONDITIONS AND COVERAGE FORM(S) AND ANY ENDORSEMENT(S), COMPLETE THE ABOVE NUMBERED POLICY.

PHILADELPHIA INSURANCE COMPANIES

Philadelphia Indemnity Insurance Company
One Bala Plaza, Ste. 100
Bala Cynwyd, PA 19004

BOND RIDER

Bond No: PB11499812250

Principal: RELIABLE HEALTHCARE LOGISTICS, LLC

Obligee: THE STATE OF NEVADA

Surety: Philadelphia Indemnity Insurance Company

Effective: August 30, 2025

It is agreed that: Adding Four Locations:

1. 751 NW 33rd Street, Suite 190, Pompano Beach, FL 33064
2. 6 Wheeling Road, Suite A, Dayton, NJ 08810
3. 5653 Creekside Parkway, Suite B, Lockbourne, OH 43137
4. 1113 Gillingham Lane, Suite A, Sugarland, TX 77478

Nothing herein contained shall be held to vary, waive, alter, or extend any of the terms, conditions, agreements or warranties of the above mentioned bond, other than stated as above. Provided, however, that the liability of the company under the attached bond as changed by this order shall not be cumulative.

Signed this 30th **day of** September **. 20** 25 **.**

Principal:

By: _____
Principal Signature

Philadelphia Indemnity Insurance Company

By: _____
John D. Weisbrot **Attorney in Fact**

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS. That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 30th day of September 20 25.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
Mortgage loans	980,210	1,060,940
Real estate	45,943	21,033
Derivatives	3,552	-
Other invested assets (cost $219,302 and $201,673)	229,008	226,716
Receivables for securities sold	329	4,072
Cash, cash equivalents and short-term investments	176,533	147,539
Cash and invested assets	11,237,195	10,754,075
Premiums receivable, agents' balances and other receivables	1,166,132	1,108,771
Reinsurance recoverable on paid loss and loss adjustment expenses	63,067	57,589
Accrued investment income	94,377	93,350
Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 6,059,913	$ 5,797,285
Unearned premiums	1,990,597	1,887,004
Reinsurance payable on paid loss and loss adjustment expenses	39,877	35,204
Federal income taxes payable	-	2,352
Ceded reinsurance premiums payable	183,308	152,393
Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
Accrued expenses and other liabilities	54,505	62,438
Total liabilities	8,815,290	8,365,456
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 16, 2028
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11499812250

Application/License No. _____

RELIABLE HEALTHCARE LOGISTICS, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 951 CLINT MOORE ROAD, SUITE A, BOCA RATON, FL, 33487 (Address of Applicant/Principal), as PRINCIPAL, and Philadelphia Indemnity Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Bala Plaza, Suite 100 BALA CYNWYD PA 19004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Aug 30, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of September, 20 25.

APPLICANT/PRINCIPAL
RELIABLE HEALTHCARE LOGISTICS, LLC
COMPANY

Authorized Representative

SURETY
Philadelphia Indemnity Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

PHILADELPHIA INDEMNITY INSURANCE COMPANY * CORPORATE SEAL * 1927 * PENNSYLVANIA

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

Bond # PB11499812250

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE, STEVEN M. VARGA OR NANCY NIGRO of J W Bond Consultants Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 15th day of September, 2025.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

To verify the bond please visit https://www.suretybond.org/validate/?code=fVhD1U1Q4EaXhXA15TXkVADg&transaction=XFkG0VQV16cwheQwRcVVdJCQ

PHILADELPHIA INDEMNITY INSURANCE COMPANY

Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(in thousands, except par value and share amounts)

Admitted Assets	As of December 31, 2024	2023
Bonds (fair value $9,153,035 and $8,720,743)	$ 9,774,560	$ 9,263,769
Preferred stocks (fair value $6,762 and $8,060)	6,762	8,060
Common stocks (cost $17,100 and $18,727)	20,298	21,946
Mortgage loans	980,210	1,060,940
Real estate	45,943	21,033
Derivatives	3,552	-
Other invested assets (cost $219,302 and $201,673)	229,008	226,716
Receivables for securities sold	329	4,072
Cash, cash equivalents and short-term investments	176,533	147,539
Cash and invested assets	11,237,195	10,754,075
Premiums receivable, agents' balances and other receivables	1,166,132	1,108,771
Reinsurance recoverable on paid loss and loss adjustment expenses	63,067	57,589
Accrued investment income	94,377	93,350
Receivable from affiliates	6,240	7,123
Federal income taxes receivable	8,824	-
Net deferred tax assets	168,818	162,612
Other assets	19,448	11,103
Total admitted assets	$ 12,764,101	$ 12,194,623

Liabilities and Capital and Surplus		
Liabilities:		
Unpaid loss and loss adjustment expenses	$ 6,059,913	$ 5,797,285
Unearned premiums	1,990,597	1,887,004
Reinsurance payable on paid loss and loss adjustment expenses	39,877	35,204
Federal income taxes payable	-	2,352
Ceded reinsurance premiums payable	183,308	152,393
Commissions payable, contingent commissions and other similar charges	310,107	298,124
Funds held	147,288	96,542
Payable to affiliates	20,596	20,862
Provision for reinsurance	78	295
Payable for securities purchased	9,021	12,957
Accrued expenses and other liabilities	54,505	62,438
Total liabilities	8,815,290	8,365,456
Capital:		
Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding	4,500	4,500
Surplus:		
Gross paid-in and contributed surplus	386,071	386,071
Unassigned surplus	3,558,240	3,438,596
Total surplus	3,944,311	3,824,667
Total capital and surplus	3,948,811	3,829,167
Total liabilities and capital and surplus	$ 12,764,101	$ 12,194,623

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2026
Commission number 1245769
Member, Pennsylvania Association of Notaries

Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 3rd day of June 2025.

Kimberly Kessleski, Notary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Reliable HealthCare Logistics, LLC — MDEG License # (if applicable): WH03466

Physical Address: 1113 Gillingham Lane, Suite A

City: Sugarland — State: TX — Zip: 77478

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton — State: FL — Zip: 33487

Telephone: 561-998-3885 Ext 406 — Website: www.reliablehealthcarelogistics.com

Licensing Company Email: SUGARLANDLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Christopher — Middle: Lane — Last: Martin

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] — SSN or ITIN [redacted] — Sex: ■ M ☐ F ☐ X

Mailing Addres[redacted]

City: San Antonio — State: TX — Zip [redacted]

Telephone: 561-998-3885 Ext 406 — Email: cmartin@rhcl3pl.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bethel University		Graduated 12/2012	
Address	**City**	**State**	**Zip**
325 Cherry Ave	Mckenzie	TN	38201
Diploma/Degree obtained, if any			
Bachelor of Science in Management and Organizational Leadership			
School Name		From - To (MM/YY – MM/YY)	
Mckenzie High School		08/86 - 05/90	
Address	**City**	**State**	**Zip**
80 Woodrow Ave	Mckenzie	TN	38201
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23 - Present	[redacted]	San Antonio	TX	[redacted]
03/20 - 04/01/2023		San Antonio	TX	
09/18 - 03/20		San Antonio	TX	
03/14 - 09/18		San Antonio	TX	
07/13 - 03/14		San Antonio	TX	
08/09 - 07/13		Jackson	TN	
From - To (MM/YY – MM/YY)		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/2022 - Present	
Business Address		**City**	**State**	**Zip**
1113 Gillingham Lane, Suite A		Sugarland	TX	77478
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 406	Logistics Manager		6,672	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			07/2019 - 08/2022	
Business Address		**City**	**State**	**Zip**
1113 Gillingham Lane, Suite A		Sugarland	TX	77478
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 406	Logistics Manager		2,426.66	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Lane Martin, **certify that as the MDEG Administrator for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements):

1. CM Have a high school diploma or its equivalent;
2. CM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Lane Martin
Print Name (First, Last)

Christopher Lane Martin
Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

Board Use Only	Date Received: 11/4/25

Chris L. Martin

[redacted]

[redacted]

EXPERIENCE:

August 2022 – Present

Site Logistics Manager / Site Leader
Reliable HeatlthCare Logistics, LLC; Sugarland, TX

- Started up 3PL site with minimal staffing to bring 2 multi billion dollar brands onboard with 3PL company.
- Lead implementation for all initiatives at San Antonio 3PL location.
- Manage >54,000 Sq. Ft Warehouse
- Facilitate all work processes to support receiving and order selection for multiple clients.
- Interface daily with clients to provide best in class pharmaceutical and GMP storage solutions.

January 2021 – August 2022

Site Logistics Manager / Site Leader
Woodfield Distribution, LLC; San Antonio, TX

- Started up 3PL site with minimal staffing to bring 2 multi billion dollar brands onboard with 3PL company.
- Lead implementation for all initiatives at San Antonio 3PL location.
- Manage >54,000 Sq. Ft Warehouse
- Facilitate all work processes to support receiving and order selection for multiple clients.
- Interface daily with clients to provide best in class pharmaceutical and GMP storage solutions.

August 2017 – December 2020

High Performance System Manager
The Nature's Bounty Company; San Antonio, TX – Prescott, AZ

- Lead implementation for all HPS (High Performance System) initiatives at San Antonio and Prescott sites, utilize lean and TPM methodology, combined with HPO (High Performing Organization) methodology to improve and sustain breakthrough (>20% results) improvements year over year
- Mentor and Coach Site Leaders, Site Senior Quality Managers, Site Maintenance

Excellence Managers, Site EHS Leaders on all functions with HPS- SOY (Site of the Year) results have improved year of year since my support of the entire team- Currently 1st out of 10 sites

- Facilitate DDS (Daily Direction Setting) process for sites, business unit and operating teams, including daily, weekly, monthly and quarterly tactical and strategic execution of business deliverables
- Lead yearly fiscal year strategy for all site functions related to delivering business objectives- List savings attained
- Implemented standardized process DAY- Downtime, Attrition and Yield to help improve yield results by 8% since last FY 19
- Integrated new process at all levels of DDS to help improve schedule adherence results year of year by 7% annually
- Site trainer for RCA (Root Cause Analysis) training

November 2014- August 2017

Quality Technologist

The Nature's Bounty Company; San Antonio, TX

- Improved losses by over 50% from process study on color separation, annual savings from color stability are in excess of 1MM annually
- Developed process to eliminate scrap for all site SKU's, standardized formula summary requirements for all products to specify color amounts used to reduce waste and help improve yield results
- Represented Texas during DMS (Daily Management System) project to develop centerline process for supply chain rollout throughout manufacturing and warehouse distribution centers, result is enhanced centerlines on Mogul has reduced holds by 18%

July 2013- November 2014

Quality Initiatives Team Leader I

HEB Manufacturing QA Division; San Antonio, TX

- Lead auditor for all 6 food manufacturing and 2 non-food manufacturing facilities within QA (Quality Assurance) for both TWI (Training Within Industry) & MMM /AM (Manufacturing Maintenance Management / Autonomous Maintenance).

- Audit the TWI program to document any QA non-conformities which are inconsistent with SQF quality procedures and processes.

- Audit the TWI program for any new equipment installations to document any QA non-conformities which are inconsistent with SQF quality procedures and processes.

- Audit the MMM program currently through Step 3 of AM to document any equipment non-conformities which are consistent with TPM (Total Productive Maintenance) procedures and processes.

- Coach facility leaders, continuous improvement leaders, operations leaders to implement successful strategies to deliver KPI's necessary for the business

- Teach JI (Job Instruction) & JR (Job Relations) methodology to exempt and nonexempt employees in the HEB University Retail Support Center

June. 2012 – Jul 2013

Quality Process Engineer Line 5/6
Pringles Manufacturing, Kellogg (previously part of Procter & Gamble); Jackson, TN

- Site trainer for Food Safety (Site GMP's, HACCP).

- Daily direct coaching of 4 on-shift quality leaders. Ensure RCA (Root Cause Analysis) is complete for all quality alerts, quality holds, and quality incidents.

- Analyze quality incident trends and develop systemic plans to address all quality outages.

- Liaison between Quality Department and outside regulatory agencies and auditors (FDA, TDA, Rabbi).

- Lines 5-6 change management approver for quality related improvements/Kaizens.

- Review ORA (Overall Risk Assessment) for Lines 5-6 during project design and planning stages, with direct emphasis on impacts to quality.

- Perform quality compliance walkthrough prior to construction turnover to Plant Operations of all projects on Lines 5-6.

Sept. 2010 –June. 2012

Quality Process Engineer Line 5/6
Pringles Manufacturing, Procter & Gamble; Jackson, TN

- Site trainer for Food Safety (Site GMP's, HACCP).

- Daily direct coaching of 4 on-shift quality leaders. Ensure RCA (Root Cause Analysis) is complete for all quality alerts, quality holds, and quality incidents.

- Analyze quality incident trends and develop systemic plans to address all quality outages.

- Liaison between Quality Department and outside regulatory agencies and auditors (FDA, TDA, Rabbi).

- Lines 5-6 change management approver for quality related improvements/Kaizens.

- Review ORA (Overall Risk Assessment) for Lines 5-6 during project design and planning stages, with direct emphasis on impacts to quality.

- Perform quality compliance walkthrough prior to construction turnover to Plant Operations of all projects on Lines 5-6.

- Represented department on site AM pillar team- Lead site CIL program

Oct. 2009 – Sep. 2010

Team Leader Lines 5-6
Pringles Manufacturing, Procter & Gamble; Jackson, TN

- Direct coaching of all team members on work and development plans, safety, quality, line reliability.

- Qualified in both Making and Packing areas of each Pringles line.

- Led multiple FI (Focused Improvement) team on 7-step process with packing area equipment to help reduce or eliminate equipment stops and reduce effort loss.

June 2006 – Oct. 2009

Quality Systems Engineer Lines 5-8
Pringles Manufacturing, Procter & Gamble; Jackson, TN

- Start-up manager for $3MM line initiative installed to reduce inventory.

- Implemented new systems for 4 operating teams to help reduce losses associated with safety, quality or line reliability issues.

- Led 7 autonomous maintenance teams through Step 4 to help restore equipment to base condition.
- Led department through implementation of Step 5 of autonomous maintenance
- Co-Lead site team on lead model for implementation of Step 6 of autonomous maintenance

- Daily direct coaching of 4 on-shift quality leaders. Ensure RCA (Root Cause Analysis) is complete for all quality alerts, quality holds, and quality incidents.

- Lines 5-6 change management approver for quality related improvements/Kaizens.

- Analyze quality incident trends and develop systemic plans to address all quality outages.
-

Sept. 1996 – June 2006

Manufacturing Quality Technician / Back up Team Leader Lines 1-8
Pringles Manufacturing, Procter & Gamble; Jackson, TN

- Filled in for Team Leader as needed.

- Direct coaching responsibility for all floor workgroups.
- Direct responsibility for follow up on all team related quality issues, including root cause analysis and follow up.

1994-1996 **Production Order Puller** (Formerly H.I.S.) Henry I. Siegel

1990 – 1994 **Weather Observer**
United States Air Force

CERTIFICATIONS & SKILLS:

- ADKAR Trained 2018
- Certified Quality Auditor (ASQ) June 2014
- Job Instruction (TWI) Certified HEB September 2013
- SQF Practitioner Certified (Post-Farm Gate) September 2013
- Job Relations (TWI) Certified HEB August 2013
- Implementing SQF 2000 – Level 3 Systems Internal Certification HEB July 2013
- Advanced HACCP Internal Certification HEB July 2013
- HACCP (Hazard Analysis and Critical Control Points) SQF Certified, 2013
- GFSI (Global Food Safety Initiative) AIB Trained 2012
- HACCP (Hazard Analysis and Critical Control Points) AIB Trained, 2010, 2012
- GSUM (Global Start-Up Management) Qualified, 2009
- Authorizer for the following areas: Hot Work, Confined Space, and Welding
- Site owner for the following systems: Equipment Inspections (Safety), Clean Inspect, and Lubrication
- Proficient in SAP; MS Office, including Word, PowerPoint, Excel, Access, and Outlook; and Lotus Notes

HONORS & AWARDS:

- Power of You Gold Award 2012
- Power of You Silver Award 2010
- Received 100 recognition shares of P&G stock (Feb 2004)

EDUCATION:

December, 2012

B.S. in Management and Organizational Leadership
Bethel University, McKenzie, TN
Graduated *Summa Cum Laude* (4.0 GPA)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Reliable HealthCare Logistics, LLC

Pharmacy/Wholesaler License # (if applicable): WH03466

Physical Address: 1113 Gillingham Lane, Suite A

City: Sugarland State: TX Zip: 77478

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext 406 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: SUGARLANDLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Christopher Middle: Lane Last: Martin

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: San Antonio State: TX Zip: [redacted]

Telephone: 561-998-3885 Ext 406 Email: cmartin@rhcl3pl.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bethel University		Graduated 12/2012	
Address	**City**	**State**	**Zip**
325 Cherry Ave	Mckenzie	TN	38201
Diploma/Degree obtained, if any			
Bachelor of Science in Management and Organizational Leadership			

School Name		From - To (MM/YY – MM/YY)	
Mckenzie High School		08/86 - 05/90	
Address	**City**	**State**	**Zip**
80 Woodrow Ave	Mckenzie	TN	38201
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23 - Present	[redacted]	San Antonio	TX	[redacted]
03/20 - 04/01/2023		San Antonio	TX	
09/18 - 03/20		San Antonio	TX	
03/14 - 09/18		San Antonio	TX	
07/13 - 03/14		San Antonio	TX	
08/09 - 07/13		Jackson	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Reliable HealthCare Logistics, LLC			08/2022 - Present	
Business Address		**City**	**State**	**Zip**
1113 Gillingham Lane, Suite A		Sugarland	TX	77478
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 406	Logistics Manager		6,672	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Woodfield Distribution, LLC			07/2019 - 08/2022	
Business Address		**City**	**State**	**Zip**
1113 Gillingham Lane, Suite A		Sugarland	TX	77478
Phone	**Title**		**Number of Employed Hours**	
561-998-3885 Ext 406	Logistics Manager		2,426.66	
Description of Duties				
Please see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Lane Martin, **certify that as the designated representative for**

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CM I am at least 21 years of age;
3. CM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Lane Martin
Print Name (First, Last)

Christopher Lane Martin
Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Lane Martin

Print Name (First, Last)

Christopher Lane Martin

Original Signature (electronic, copies or stamps not accepted)

10/29/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, Christopher Lane Martin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Christopher Lane Martin

Original Signature

10/29/2025

Date

Subscribed and Sworn to before me this 29th day of October 2025.

Hernandes

Notary Public Signature

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Reliable HealthCare Logistics, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH03466

Physical Address: 1113 Gillingham Lane, Suite A

City: Sugarland State: TX Zip: 77478

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: SUGARLANDLICENSE@RHCL3PL.COM

Section 2: Personal Information

First: Benjamin Middle: Ephraim Last: Maizel

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☑ M ☐ F ☐ X

Mailing Address[redacted]

City: Dunedin State: FL Zip[redacted]

Telephon[redacted] Email: bmaizel@rhcl3pl.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fairleigh Dickenson University		1980-1983	
Address	**City**	**State**	**Zip**
1000 River Rd	Teaneck	NJ	07666
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Florida Gainesville		9/1975 - 6/1979	
Address	**City**	**State**	**Zip**
1478 Union Rd	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018 - Present	[redacted]	Dunedin	FL	[redacted]
2007-2018		Palm Harbor	FL	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fairleigh Dickenson University			
Address	**City**	**State**	**Zip**
1000 River Rd	Teaneck	NJ	07666
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of Florida Gainesville			
Address	**City**	**State**	**Zip**
1478 Union Rd	Gainesville	FL	32611
Diploma/Degree obtained, if any			
Bachelor of Science, Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]	Dunedin	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Reliable HealthCare Logistics, LLC			08/01/2025 - Present
Business Address	**City**	**State**	**Zip**
951 Clint Moore Road, Suite A	Boca Raton	FL	33487
Phone	**Title**		
561-998-3885 Ext 207	CEO		

Description of Duties

CEO of Third-Party Logistics company, focused on the healthcare industry, specifically Generic Pharmaceutical companies.

Business Name			From - To (MM/YY – MM/YY)
Trusted Partner Pharma Logistics			01/2023 - Present
Business Address	**City**	**State**	**Zip**
3783 Winning Stakes Way	Mason	OH	45040
Phone	**Title**		
716-553-9641	CEO & Co-Founder		

Description of Duties

CEO & Co-Founder, Formed specific company to launch a generic focused 3PL

Business Name			From - To (MM/YY – MM/YY)
DiRx Inc			03/21 - 07/23
Business Address	**City**	**State**	**Zip**
2 TOWER CENTER Blvd Floor 12	East Brunswick	NJ	08816
Phone	**Title**		
(908) 356-0764	COO		

Description of Duties

Responsible for all aspects of physical pharmacy, product acquisition, pharmacy team including Customer Service, Outreach and Fulfillment teams, and Compliance.

Business Name			From - To (MM/YY – MM/YY)
McKesson			01/2018-03/2020
Business Address	**City**	**State**	**Zip**
	Mason	OH	
Phone	**Title**		
	Vice President		

Description of Duties

Completed Operational, Financial, Customer Service transition to RxCrossroads

Business Name			From - To (MM/YY – MM/YY)
RXTPL LLC			01/2012 - 12/2017
Business Address	**City**	**State**	**Zip**
	Mason	OH	
Phone	**Title**		
	President		

Description of Duties

CREATED a 3rd Party Logistics company for pharmaceutical manufacturers. Oversaw all aspects of the company, growing from zero to over 50 international manufacturers and growing business year over year

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Maizel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach.

I, Benjamin Maizel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/29/2025.

Date

Subscribed and Sworn to before me this 29th day of October 2025

Notary Public Signature

LIZBETH HERNANDES
Commission # HH 334149
Expires November 20, 2026

(Seal)

Employee list for our 1113 Gillingham Lane, Suite A, Sugarland, TX 77478

Cooksey, Dylan B	Sugar Land, Texas
Moncada, Katherine	Sugar Land, Texas
Moreno, Haydee	Sugar Land, Texas
Ngoy, Freddy	Sugar Land, Texas
Rodriguez Torres, Orgides	Sugar Land, Texas
Shepard, Shyanne R	Sugar Land, Texas

IRS.gov

EIN Assistant

Your Progress: 1. Identity 2. Authenticate 3. Addresses 4. Details **5. EIN Confirmation**

Congratulations! Your EIN has been successfully assigned.

EIN Assigned: **88-1175079**

Legal Name: **RELIABLE HEALTHCARE LOGISTICS LLC**

IMPORTANT:

Save and/or print this page and the confirmation letter below for your permanent records.

The confirmation letter below is your official IRS notice and contains important information regarding your EIN.

CLICK HERE for Your EIN Confirmation Letter Help with saving and printing your letter

Once you have saved or printed your letter, click "Continue" to get additional information about using your new EIN. Continue >>

Help Topics

- What if I do not have access to a printer at this time?
- Can I access this letter at a later date?

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See *Specific Instructions* on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Reliable HealthCare Logistics, LLC

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only one of the following seven boxes.

☐ Individual/sole proprietor ☐ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☑ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) C

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions ☐

5 Address (number, street, and apt. or suite no.). See instructions.

951 Clint Moore Road, Suite A

Requester's name and address (optional)

6 City, state, and ZIP code

Boca Raton, FL 33487

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

8	8	–	1	1	7	5	0	7	9

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** [signature] **Date** 8-14-2025

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

Dated: July 03, 2025
The following is ORDERED:

Jennie D. Latta
UNITED STATES BANKRUPTCY JUDGE

UNITED STATES BANKRUPTCY COURT
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

IN THE MATTER OF:

RELIABLE HEALTHCARE LOGISTICS, LLC	NO.: 24-20252-JDL
Debtor	CHAPTER 11

ORDER CONFIRMING PLAN OF REORGANIZATION FOR RELIABLE HEALTHCARE LOGISTICS, LLC BY TRUSTED PARTNER PHARMA LOGISTICS LLC AS COMPETING PLAN OF REORGANIZATION

Upon Trusted Partner Pharma Logistics, LLC filed a Competing Plan of Reorganization on April 3, 2025 (ECF No. 318), notice being sent to all creditors and parties in interest with plans and ballots of Reliable Healthcare Logistics, LLC ("Reliable") (ECF No. 321) the Court held confirmation hearing on June 26, 2025 based upon the Tally of Ballots for each competing Plan, objection filed by US Trustee; Limited Objection filed by Creditor Pool 5 Industrial TX, LLC ("Pool 5"); and the Limited Objection filed by BCI IV

Palm Beach CC LLC ("BCI IV") . At the hearing on these matters, the Court found the competing Plan of Reliable according to Tally of Ballots was not capable of confirmation and proceeded on the Tally of Ballots of TPPL and the cram down provisions of 11 U.S.C. Section 1129 for confirmation. After testimony of Benjamin Maziel, witness for TPPL on the elements for confirmation; argument and statements of counsel the Court found TPPL Plan confirmable as orally amended at the hearing and makes findings of fact and conclusions of law as follows:

1. The TPPL Plan complies with the applicable provisions of this title.
2. TPPL complies with applicable provisions of Title 11.
3. TPPL based on testimony of the witness has proposed the Plan in good faith and not by any means forbidden by law.
4. TPPL Plan and witness disclosed all the principals of reorganized company and all payments to be made or to be made acquiring property under the Plan, for services or for costs and expenses in or in connection with the case, or in connection with the Plan and incident to the case, has been approved by, or is subject to the approval of the court as reasonable.
5. TPPL by Plan and witness has disclosed the identity and affiliations of any individual proposed to serve, after confirmation of the plan, as a director, officer, or voting trustee of the debtor, an affiliate of the debtor participating in a joint plan with the debtor under the plan and such appointment to such office is consistent with the interests of creditors and public policy. There is no insider that will be employed or retained by the reorganized debtor.
6. With respect to each impaired class of claims or interest the impaired class has

accepted the TPPL Plan or will receive or retain under the plan on account of such claim or interest property of a value, as of the effective date of the plan, that is not less than the amount that such holder would so receive or retain if the debtor were liquidated under Chapter 7 of this title on such date.

7. Class 3.04 Pre-Petition Unsecured Claim of BCI IV treatment is amended to provide as follows:

Class 3.04 consists of the allowed unsecured claim due to BCI IV Palm Beach, LLC ("BCI") for prepetition rent arrearages in the amount of $550,915.57 (the "Cure Amount") for the lease of non-residential real property located at 951 Clint Moore Road, Boca Raton, Florida (the "Lease"). Upon the Effective Date, the Lease shall be assumed by the Debtor. BCI shall retain its pre-petition security deposit as security for the lease. Upon the Effective Date, BCI shall have an allowed unsecured claim for the Cure Amount and the Debtor shall pay thirty percent (30%) of the Cure Amount. The balance of the Cure Amount shall be paid in 9 equal monthly installments commencing thirty days following the initial payment. Upon written notice from BCI of any default by the Debtor in the payment of the Cure Amount, the Debtor shall have ten (10) days to cure such default. Any defaults with respect to the payment of ongoing rent payments shall be governed by the terms of the Lease.

8. Class 4.04 Pre-Petition Unsecured Claims of Certain Lawsuits is amended to specify in the Encube litigation that the Reorganized Debtor will dismiss the Delaware litigation against Encube with prejudice and Encube will not receive any distribution on its claim against the Debtor; that the Debtor's objection to

Encube's claim is deemed compromised and settled and by this amendment Encube accepts the Plan and all costs associated with such litigation will be paid by each party for their own fees and expenses.

9. Class 5 Interests of Reliable Healthcare Logistics Investments, LLC, pre-petition sole membership interest in the Debtor, is extinguished on the Effective Date. TPPL is contributing new capital to the reorganized debtor in the amount of $500,000 in exchange for one hundred percent (100%) of the membership interest in the reorganized Debtor. The Reorganized Debtor continues to be the same legal entity upon confirmation. The new capital will be paid on or before the Effective Date in full. Class 5

10. All property comprising of the Estate (including causes of action, but excluding property that has been abandoned pursuant to an order of the Bankruptcy Court) shall vest in the Reorganized Debtor, as of the Effective Date, free and clear of all Claims, liens, charges, encumbrances, rights and Interests of creditors and equity security holders. As of the Effective Date, the Reorganized Debtor may operate its business and use, acquire, and dispose of property and settle and compromise Claims or Interests without supervision of the Bankruptcy Court, free of any restrictions of the Bankruptcy Code or Bankruptcy Rules, other than those restrictions expressly imposed by this Plan and Confirmation Order. Except as otherwise provided in any provision of the Plan, upon entry of the Order of Confirmation and pursuant to 11 U.S.C. § 1141(b) and (c), any and all property of the Estate shall vest in the reorganized Debtor free of all liens, security interests, mortgages or other interests in property secured by an Allowed Claim except as

expressly provided for in the Plan. Pursuant to §1146(c), no stamp taxes, transfer tax or Tennessee indebtedness tax or other similar taxes shall be due as a result of the making or delivery of an instrument of transfer pursuant to the Plan.

11. Paragraph K.(4) on Exculpation and Limitation of Liability of TPPL Plan is hereby deleted in full upon objection of US Trustee.

12. Pursuant to this Court's order of March 31, 2025, the proof of claim of Pool 5 Industrial TX, LLC is disallowed. Pool 5 has appealed the Court's order. In the event Pool 5's claim becomes an allowed administrative expense claim or allowed unsecured claim, then such claim shall be deemed incorporated into the Plan with the same priority and classification as such other similarly situated administrative expense claims (Class 1) and/or pre-petition unsecured claims related to rejected/terminated leases (Class 4.01).

13. The Plan will become effective on or before the first business day following fourteen (14) days after the Confirmation Order becomes a Final Order. Upon Final Order the Reorganized Debtor will have full access to all accounts, books and records of Reliable.

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED THAT the objections to Plan are denied and the Court makes findings of fact and conclusions of law in regard to the Plan and confirmation as stated above. There is at least one accepting impaired class voting for Plan of TPPL. The TPPL Plan is confirmed based upon the testimony of the witness and amendments as stated herein.

Approved

/s/ Toni Campbell Parker

TONI CAMPBELL PARKER (TN # 6984)
ATTORNEY FOR TPPL
45 North BB King Blvd,. SUITE 201
MEMPHIS, TENNESSEE 38103
Tparker002@att,net
(901) 483-1020

/s /s/ Carrie Ann Rohrscheib,
Carrie Ann Rohrscheib
Attorney for US Trustee

/s/ R. Campbell Hillyer
R. Campbell Hillyer
Attorney for BCI IV Plam Beach CC LLC and Pool 5D

/s/ David W. Houston IV
David W. Houston IV
Attorney for Encube

/s/ Michael P. Coury
Michael P. Coury
Attorney for Reliable Healthcare Logistics, LLC

CC

Debtpr:

Office of US Trustee
All creditors of this estate and all parties on the mailing matrix of Debtor

4904-7001-6082, v. 1

Reliable HealthCare Logistics, LLC

License List

RHL Facility	State	License Number	License Type	License Issue Date	License Expiration Date
RHL TX	Alabama	196453	Third-Party Logistics Provider	9/8/2023	12/31/2025
RHL TX	Alaska	201641	Third-Party Logistics Provider	10/26/2022	6/30/2026
RHL TX	Arizona	L000446	Third-Party Logistics Provider	11/16/2023	10/31/2027
RHL TX	Arkansas	WD05799	Wholesale Distributor License	1/9/2023	12/31/2026
RHL TX	Colorado	TPLP.0000057	Third Party Logistics Provider	4/12/2023	10/31/2026
RHL TX	Connecticut	CSW.0005201	Wholesaler of Drugs, Cosmetics & Medical Devices	7/1/2023	6/30/2026
RHL TX	Delaware	A4-0013069	Pharmacy - Wholesale	5/1/2023	9/30/2026
RHL TX	Distric of Columbia	DM2300111	Non-Resident Distributor	6/12/2023	6/30/2026
RHL TX	Florida	02426	Third Party Logistics Provider	2/20/2023	2/28/2027
RHL TX	Georgia	PHWH005556	Wholesaler Pharmacy	4/21/2023	6/30/2027
RHL TX	Illinois	278000186	Wholesale Drug Third Party Logistics Provider	6/21/2023	12/31/2026
RHL TX	Indiana	94000333A	Third Party Logistics Provider	9/19/2025	9/30/2026
RHL TX	Kansas	23-126186	Third Party Logistics Provider	9/12/2025	6/30/2026
RHL TX	Kentucky	TPL00509	Third Party Logistic	8/25/2025	6/30/2026
RHL TX	Louisiana	11718	Distributor of Legend Drugs or Legend Devices	9/10/2025	12/31/2025
RHL TX	Maine	WH70003428	Pharmaceutical Wholesaler	4/12/2023	12/31/2025
RHL TX	Michigan	5306007336	Wholesale Distributor	8/16/2023	8/16/2027
RHL TX	Minnesota	900220	Third Party Logistics Provider	8/11/2023	10/31/2026
RHL TX	Mississippi	18636/16.3a	Drug Facility - 3rd Party Logistics (Non-Resident)	3/7/2023	12/31/2025
RHL TX	Missouri	2025041073	Third-Party Logistics Provider	9/19/2025	10/31/2027
RHL TX	Montana	PHA-WDD-LIC-117721	Wholesale Drug Distributor License	3/2/2023	11/30/2025
RHL TX	Nevada	WH03466	Wholesaler	7/14/2023	10/31/2026
RHL TX	New Hampshire	08388	Man/Dist/Whole/Broker	1/17/2023	8/29/2027
RHL TX	New Jersey	5006197	Wholesale	12/21/2022	1/31/2026
RHL TX	New Mexico	WD20220405	Temporary - Third Party Logistics Provider Permit	9/5/2025	12/31/2027
RHL TX	North Carolina	1696	Third Party Logistics Provider	1/6/2023	12/31/2025
RHL TX	Ohio	0170000113	Third Party Logistics - Category 2	3/21/2023	6/30/2027
RHL TX	Oklahoma	88-L-9227	3PL Provider	9/12/2025	9/30/2026
RHL TX	Oregon	DDA-0000637	Drug Distribution Agent	3/13/2023	9/30/2026
RHL TX	Pennsylvania	3000010484	Distributor of Prescription Drugs	3/5/2023	3/31/2026
RHL TX	Rhode Island	DIS03871	Drug Wholesaler - Out of State	1/26/2023	9/30/2026
RHL TX	South Carolina	23424	Non-Resident Third Party Logistics Provider	8/26/2025	6/30/2026
RHL TX	Tennessee	8453	Third Party Logistics	1/3/2023	1/31/2027
RHL TX	Texas	1003550 1002129	Wholesale Distributor of Prescription Drugs & Food Wholesaler & Device Distributor	12/27/2022 12/06/2023	8/22/2026 11/1/2025
RHL TX	Utah	14243257-1714	Pharmacy - Class E Business	9/8/2025	9/30/2027
RHL TX	Vermont	159.0000275	Third Party Logistics Provider	10/14/2025	7/31/2027
RHL TX	Virginia	0242000262	Non-Resident Third Party Logistics Provider	8/14/2023	2/28/2026

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
DRUGS AND MEDICAL DEVICES

ESTABLISHMENT INSPECTION REPORT

FIRM:	Reliable Healthcare Logistics LLC	**DATE:**	05/07/2025
ADDRESS:	1113 Gillingham Ln. Ste. A	**INVESTIGATOR:**	Jonathan Vazquez
CITY, STATE, ZIP:	Sugar Land, TX 77478	**CFN:**	2108777
TELEPHONE:	281-886-5600	**FDA FEI:**	3024548814

SUMMARY OF FINDINGS:

This was a routine inspection under #251425 (2504) and #251414 (2501) conducted by the Department of State Health Services (DSHS), Drugs and Medical Devices (DMD) of a firm who is currently licensed as an OTC Multiple Product Distributor (OTC drugs, medical devices, and food) and Prescription Drug Distributor. The firm was previously inspected 10/23/2023 and endorsed with Voluntary Action Indicated No Warning due to the lack of maintaining temperature logs for the storage of prescription drugs and the lack of maintaining a valid OTC Multiple Product License.

The inspection #251425 (2504) and #251414 (2501) resulted in a Notice of Inspection letter issued with no observations cited.

Reliable Healthcare Logistics operates as a 3PL prescription and nonprescription drug, medical device, and food distributor to wholesalers and retailers nationwide.

ADMINISTRATIVE DATA:

Name of Firm	Reliable Healthcare Logistics LLC
Address of Firm	1113 Gillingham Ln. Ste. A
City, State, Zip Code	Sugar Land, TX 77478
Telephone number(s)	281-886-5600
Fax Number	None
FDA FEI	3024548814
Investigator(s)	Jonathan Vazquez
Date(s) of Inspection	05/07/2025
Website Address	https://www.reliablehealthcarelogistics.com/
Email address	fngoy@rhcl3pl.com lhernandes@reliablehealthcarelogistics.com
Credentials presented to	Mr. Freddy Ngoy, Operations Manager Ms. Lizabeth Hernandes, Licensing Specialist (via telephone)

Form(s) issued	NOI under IDM #251425 (2504) and #251414 (2501)

HISTORY:

CEO/President/Owner	President – Position Vacant Mr. Mike MacKay, COO Ms. Cheryl Oleski, Director of Quality
Legal Status of Firm	07/01/2022 in Delaware
Corporate Mailing Address	951 Clint Moore, Suite A, Boca Raton, Florida
Days/Hours of Operation	Monday – Friday; 8:30AM – 5:00PM
Time in Operation	2015
Time at Location	2022
Facility Size	50,000 square feet
Number of Employees	5 employees
G.A.S	Firm paid level 1 fee: < $200k
Related Firms/Locations	Boca Raton, FL, Pompano Beach, FL, Dayton, NJ, Lockbourne, OH
Licenses	OTC Multiple Product Distributor (License #1002129, Exp: 11/01/2025) Prescription Drug Distributor (License #1003550, Exp: 08/22/2026)
Distribution	Nationwide

JURISDICTION:

The firm distributes prescription and nonprescription drugs, medical devices, and food such as:

- Antibiotics
- Lidocaine
- Pain Medications
- Dental Anesthetics
- Cough Medications
- Wound treatments
- Infusion kits
- Infusion pumps
- Braces
- General Hospital Supplies
- Bottled Water

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITES:

I presented my credentials and provided verbal notice of inspection to Mr. Freddy Ngoy, Operations Manager and Ms. Lizabeth Hernandes, Licensing Specialist (via telephone).

Mr. Freddy Ngoy, Operations Manager and Ms. Lizabeth Hernandes, Licensing Specialist provided the facts and information in this report. Mr. Ngoy reports to Ms. Hernandez who reports to Ms. Cheryl Oleski, Director of Quality who reports to Mr. Mike MacKay, COO. Mr. Mike MacKay, COO was identified as the most responsible individual for the firm. All regulatory correspondence should be directed to Mr. Mike MacKay, COO at the listed corporate address.

SUPPLIERS:

The firm receives prescription and nonprescription drugs, medical devices, and food from Brookfield Pharmaceuticals (License #1002407, Exp: 01/25/2026) (Brookfield, WI), DXM Pharmaceutical (License #1000356, Exp: 06/07/2025) (Katy, TX), Eitan Medical (Aliso Viejo, CA), Emersa Waterbox (Brea, CA), FEMSelect (License #1003582, Exp: 09/25/2026) (Sugar Land, TX) and Tri Med Distributors (Osborne Park, WA).

OPERATIONS

Reliable Healthcare Logistics operates a 3PL. The firm distributes prescription and nonprescription drugs, medical devices, and food for clients. At approximately 50,000 square feet, it consists of a lobby, a workspace, a conference room, offices, and a warehouse. Product is organized in the warehouse depending on product type. The firm organizes products on rows of 8 shelfs. The firm does maintain a designated quarantine area and a walk-in refrigerated space for prescription drugs. The firm uses the Web Management System Day Tex to monitor inventory. Temperature regulation of prescription drugs is monitored with the Immonit software. The firm is monitored by a series of cameras and doorway security codes. The firm maintains the required standard operating procedure for receipt, distribution, inventory, storage, recall, security, quarantine, loss/theft, and disaster preparedness.

DISTRIBUTION:

The firm distributes their products to retailers and wholesales per request of their clients. Distribution recipients include AmericourceBergan, Cardinal Health, McKesson, Walmart, and CVS. New orders are received through the Day Texas software that consist of customer identification and order details. The firm distributes nationwide using UPS, FedEx, and trucking service provided by clients.

VOLUNTARY CORRECTIONS:

The following observations were cited during the previous inspection on 10/23/2023:

> **Under the 2501 license:**
> **The firm lacks appropriate manual, electrochemical, or electronic temperature and humidity recording equipment, devices or logs to document proper storage of prescription drugs. Notes: Specifically, the firm has failed to provide temperature logs for the storage of prescription**

drugs. Mr. Bales has indicated that he will send a temperature log via email.

During the inspection Ms. Cheryl Oleski, Director of Quality provided records of daily temperature logs for the storage of prescription drugs ***(Exhibits 1 & 2)****. The cost associated with this correction is unknown.*

Under 2504 License (this previous Versa entry is null voided since the firm licensed and is under a different Versa Entry)

Firm is engaged in the distribution of devices without a valid device distributor license from the Texas Department of State Health Services for the inspected place of business. Notes: Specifically, the firm is engaged in the receipt and distribution of a microbe infusion set (Lot #1360.0780.23). The firm was unable to present evidence of a current Multiple Product License.

Specifically, the firm is engaged in the receipt and distribution of a probiotic dietary supplement. The firm was unable to present evidence of a current Multiple Product License. Contact DSHS at (512) 834-6626 or (512) 834-6727 for multiple product licensing assistance. Go to https://www.dshs.state.tx.us/fdlicense if any additional information is needed.

The firm licensed as an OTC Multiple Distributor after the inspection on 10/23/23 (License #1002129, Exp: 11/01/2025). The cost associated with this correction is $520 for the OTC Multiple License.

OBJECTIONABLE CONDITIONS/DISCUSSION WITH MANAGEMENT:

I met with Mr. Freddy Ngoy, Operations Manager at the conclusion of my inspection and issued the non-violative NOI letters to him. Mr. Freddy Ngoy, Operations Manager signed the NOI letters and was provided copies for the firm's records.

There were no observations cited on the NOI letters issued to management at the conclusion of the inspection.

EXHIBITS:

1. JGV-001 – Recent temperature log for prescription drugs
2. JGV-002 – Recent temperature log for prescription drugs

NOTICE OF INSPECTION LETTERS/UPLOADED FORMS:

Notice of Inspection letter for inspection #251424 (2504)
Notice of Inspection letter for inspection #247205 (2501)

/s/ Jonathan Vazquez

Jonathan Vazquez, R.S.
Consumer Protection Division
Food & Drug Unit
Drugs and Medical Devices Branch – Inspections

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Trilliant Surgical, LLC

Physical Address: 727 N. Shepherd Dr. Suite 100

City: Houston State: TX Zip: 77007

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin State: OH Zip: 43017

Telephone: 800-321-9549 Website: www.djoglobal.com

Name of Designated Representative (DR): Gary Opperman

Licensing Company Email: licensure@cardinalhealth.com DR Email: gary.opperman@enovis.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/30/25
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Curiteva
Address: 25127 Will McComb Drive City: Tanner State: AL Zip: 35671
Name: Arcamed
Address: 5101 Decatur Blvd. Ste A City: Indianapolis State: IN Zip: 46241
Name: ECA Medical
Address: 193 Anchor Court Newbury Park City: Newbury Park State: CA Zip: 91320
Name: Dunamis Medical
Address: 509 E Commerce St, Suite C City: Greenville State: AL Zip: 36037

Section 4: Publicly Traded Corporation

State of Incorporation: N/a
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: TX
Parent Company (if any): Encore Medical, L.P
Corporation/Organization Name: Trilliant Surgical, LLC
Mailing Address: 727 N. Shepherd Dr, Suite 100
City: Houston State: TX Zip: 77007
Telephone: 800-321-9549 Email: licensure@cardinalhealth.com
Contact Person Name: LaToyia Martin

Section 6: Partnership

Partnership Name: N/a
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/a
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Trilliant Surgical, LLC

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/30/25

Date

Board Use Only	Date Received: 11/12/25	Amount: $1000 CK 109360547

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Trilliant Surgical LLC
727 N Shepherd Dr
STE 100
Houston, TX 77007
Registration Number: 3007420745
FEI Number*: 3007420745
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Trilliant Surgical[6]
727 N. Shepherd Dr.
STE 100
Houston, TX US 77007
Owner/Operator Number: 10027494[7]

Official Correspondent:
Vladislava Zaitseva
727 N. Shepherd Dr.
STE 100
Houston, TX 77007
Phone: 800-3219549

Verified 11/13/25 MH

* Firm Establishment Identifier (FEI) should be used for identification of entities within the Imports message set

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Page Last Updated: 01/06/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1 888 INFO FDA (1 888 463-6332)
Contact FDA

USA.gov

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enovis™

DJO, LLC, an Enovis company
5919 Sea Otter Place, Suite 200
Carlsbad, California 92010-6750
United States

(800) 321-9549 Toll Free
(800) 457-4221 Fax
enovis.com

DJO

November 3, 2022

Subject: Delegation of Authorization for DJO, LLC

The undersigned, Bradley J. Tandy, SVP & General Counsel, an Authorized Officer of DJO, LLC, hereby delegates to Keegan Chamberlain, Director of Quality Management, and LaToyia Martin, Manager of Quality Management, employees of Cardinal Health 200, LLC, the authority to sign for all documents, applications, and submissions, and other related instruments required for the licensing and legally required permits filed on behalf DJO, LLC and that this delegation of authority is subject to revocation, by any officer of DJO, LLC at any time and shall occur automatically when Keegan Chamberlain or LaToyia Martin ceases to be an employee of Cardinal Health 200, LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain or LaToyia Martin prior to this date, in connection with the execution of the above-referenced matters.

Respectfully,

DJO, LLC

By: _____

Name: Bradley J. Tandy

Title: SVP & General Counsel

Date: November 03, 2022

CardinalHealth

727 N. Shepherd Dr.
Suite 100
Houston, Texas 77007

Officer Name	Title
Brian P. Hanigan	VP, Chief Counsel - Securities, Governance and M&A and Corporate Secretary
Bradley J. Tandy	Senior Vice President & Chief Legal Officer

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Trilliant Surgical, LLC is 100% Owned by Encore Medical, L.P



Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Conversion for Trilliant Surgical, LLC (file number 802945802), a Domestic Limited Liability Company (LLC), was filed in this office on February 23, 2018

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on September 30, 2025.

Jane Nelson
Secretary of State

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/medical-device-manufacturers-distributors.**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

CARDINAL HEALTH ORA FACILITY LICENSING
7000 CARDINAL PLACE
DUBLIN OH 43017

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

TRILLIANT SURGICAL LLC

727 N SHEPHERD DR STE 100
HOUSTON, TX 77007

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE MANUFACTURER

License # 1003676
Expires: April 8, 2027

NON-TRANSFERABLE

Commissioner

515223

AGENCY CUSTOMER ID: CN101292797
LOC #: Morristown

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA, LLC.	DJO, LLC 5919 Sea Otter Place, Ste. 200 Carlsbad, CA 92010-6750
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Product Coverage Carriers:

Underwriters:
40.00% Renaissance Re Syndicate 1458
17.14% AXA XL Insurance Company UK Limited
3.93% Dale Syndicate 1729
3.93% Hamilton Syndicate 4000
5.00% QBE Syndicate 5555
25.00% Harleysville Insurance Company of New York
5.00% Axis Syndicate 1686

Name Insured Schedule:

Armac, Inc.
DJO Consumer LLC
DJO Consumer LLC
DJO France
DJO LLC
DJO UK Limited
Dr. Comfort
Elastic Therapy LLC
Elastic Therapy LLC
Encore Medical
ENCORE MEDICAL, L.P. dba DJO SURGICAL
Enovis Corporation
LiteCure LLC
Matrix Orthopedics Surgical Devices
Novastep, Inc.
Ortho Pros Xpress Inc
Surgi-Care Inc.
Trilliant Surgical LLC
Lima

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CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 08/11/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, LLC.
445 SOUTH STREET
MORRISTOWN, NJ 07962-1966
Attn: morristown.certrequest@marsh.com Fax 212-948-0979

CN101292797-DJO.-GAWUP-25-26

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A :	
INSURER B : Travelers Prop. Casualty Co. Of America	25674
INSURER C : Stamet Insurance Company	40045
INSURER D : See Attached Acord 101	
INSURER E :	
INSURER F :	

INSURED
DJO, LLC
5919 Sea Otter Place, Ste. 200
Carlsbad, CA 92010-6750

COVERAGES

CERTIFICATE NUMBER: NYC-012115564-35 **REVISION NUMBER:** 7

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
C	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			LNP 5073674-11	08/15/2025	08/15/2026	EACH OCCURRENCE	$	2,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	2,000,000
							GENERAL AGGREGATE	$	4,000,000
							PRODUCTS - COMP/OP AGG	$	
								$	
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			TC2JCAP-2H532302-TIL-25	05/31/2025	08/15/2026	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
							BODILY INJURY (Per person)	$	
							BODILY INJURY (Per accident)	$	
							PROPERTY DAMAGE (Per accident)	$	
								$	
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $						EACH OCCURRENCE	$	
							AGGREGATE	$	
								$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			UB-B2335763-25-51-K (AOS)	05/31/2025	05/31/2026	X PER STATUTE [ ] OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [N] (Mandatory in NH) N / A If yes, describe under DESCRIPTION OF OPERATIONS below			UB-B2312400-25-51-R (AZ,AL,FL,GA, MA,NE,OR,SC,WI)	05/31/2025	05/31/2026	E.L. EACH ACCIDENT	$	1,000,000
							E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
D	PRODUCTS LIABILITY			LSR-PCO-00622-25 SIR: $1M EA EVENT / $2.5M AGG	08/15/2025	08/15/2026	EACH OCC / AGGREGATE		10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: DJO, LLC 5919 Sea Otter Pt Suite 200 Carlsbad, CA 92010

CERTIFICATE HOLDER

National Provider Enrollment (NPE) West
Palmetto GBA AG-495
P.O. Box 100142
Columbia, SC 29202-3142

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K42125738

Application/License No. _____

Trilliant Surgical, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 727 N. Shepherd Drive, Suite 100, Houston, TX 77007 (Address of Applicant/Principal), as PRINCIPAL, and Federal Insurance Company (Surety Company), a corporation organized under the laws of the state of Indiana (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 202B Hall's Mill Road, Whitehouse Station, NJ 08889 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 1, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of October, 2025.

Trilliant Surgical, LLC
APPLICANT/PRINCIPAL

Authorized Representative
Brian Hanigan

SIGNED and SEALED in the presence of:

Witness Matthew Barringer

Witness Kenneth Murphy

Federal Insurance Company
SURETY COMPANY

Surety Company's Representative

April D. Perez, Attorney-in-fact
print name
NV Non-Resident License #722132

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness Kimberly Leonard

Countersigned by:

n/a
Nevada Resident Agent

Posted February 20, 2020

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that FEDERAL INSURANCE COMPANY, an Indiana corporation, VIGILANT INSURANCE COMPANY, a New York corporation, PACIFIC INDEMNITY COMPANY, a Delaware corporation, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

April D. Perez

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY have each executed and attested these presents and affixed their corporate seals on this 19th day of July, 2024.

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this 19th day of July, 2024 before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(I) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(II) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this October 24, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT
Telephone (908) 903- 3493 Fax (908) 903- 3656 e-mail: surety@chubb.com

FEDERAL INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2024

(In thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash, Cash Equivalents, and ST Investments	$ (355,746)	Outstanding Losses and Loss Expenses	$10,612,093
United States Government, State and Municipal Bonds	3,847,216	Reinsurance Payable on Losses and Expenses	1,730,804
Other Bonds	9,063,626	Unearned Premiums	3,117,855
Stocks	361,584	Ceded Reinsurance Premiums Payable	417,703
Other Invested Assets	1,562,503	Other Liabilities	683,379
TOTAL INVESTMENTS	14,479,183	TOTAL LIABILITIES	16,461,834
Investments in Affiliates:		Capital Stock	20,000
Great Northern Ins. Co.	444,946	Paid-In Surplus	2,711,474
Vigilant Ins. Co.	392,348	Unassigned Funds	2,245,956
Chubb National Ins. Co.	204,099	SURPLUS TO POLICYHOLDERS	4,978,410
Chubb Indemnity Ins. Co.	185,760		
Chubb Ins. Co. of New Jersey	41,523		
Chubb Lloyds Ins. Co. of Texas	6,140		
Other Affiliates	71,980		
Premiums Receivable	2,574,791		
Other Assets	3,039,474		
TOTAL ADMITTED ASSETS	$ 21,440,244	TOTAL LIABILITIES AND SURPLUS	$21,440,244

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2024, investments with a carrying value of $569,829,993 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Federal Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2024.

Sworn before me this March 20, 2025

Senior Vice President

Notary Public

August 8, 2027
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Diane Wright, Notary Public
Philadelphia County
My commission expires August 8, 2027
Commission number 1235746
Member, Pennsylvania Association of Notaries

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Trilliant Surgical, LLC MDEG License # (if applicable) New App

Physical Address 727 N. Shepherd Dr. Suite 100

City Houston State TX Zip 77007

Mailing Address (if different from physical address) 7000 Cardinal Place, QRA

City Dublin State OH Zip 43017

Telephone 800-321-9549 Website www.djoglobal.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Gary Middle Allen Last Opperman

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITI [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 727 N. Shepherd Dr. Suite 100

City Houston State TX Zip 77007

Telephone [redacted] Email gary.opperman@enovis.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Warsaw Community High School		1992-1996	
Address	**City**	**State**	**Zip**
1 Tiger Lane	Warsaw	IN	46580
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2012-Present	[redacted]	Cypress	TX	[redacted]
~~06/~~ PTA 05/12				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Enovis (Trilliant Surgical)			01/2014 - Present	
Business Address		**City**	**State**	**Zip**
727 N. Shepherd Dr.		Houston	TX	77007
Phone	**Title**		**Number of Employed Hours**	
800-321-9549	Director, Manufacturer		1500 +	

Description of Duties

Lead manufacturing operations with a focus on medical device production, ensuring compliance with FDA regulations and ISO 13485 standards. Develop/execute strategies to enhance efficiency, quality, and scalability for device manufacturing

Business Name			From - To (MM/YY – MM/YY)	
Enovis (Trilliant Surgical)			05/2012- 01/2014	
Business Address		**City**	**State**	**Zip**
727 N. Shepherd Dr.		Houston	TX	77007
Phone	**Title**		**Number of Employed Hours**	
800-321-9549	Director of Manufacturing		1500 +	

Description of Duties

Established and scaled a state-of-the- art manufacturing facility specializing in precision medical implants. Creating CNC programs for 5-axis mills, latches, and Swiss machines, ensuring precision and reliability in device production

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
NA				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Mary Oppm
Original Signature (electronic, copies or stamps not accepted)

09/16/25
Date

I, Gary Opperman, **certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. GO Have a high school diploma or its equivalent;
2. GO Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. GO Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. GO Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gary Opperman
Print Name (First, Last)

X Gary Opperman
Original Signature (electronic, copies or stamps not accepted)

09/16/25
Date

Board Use Only	Date Received: 11/12/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Trilliant Surgical, LLC

Pharmacy/Wholesaler License # (if applicable) New App

Physical Address 727 N. Shepherd Dr. Suite 100

City Houston State TX Zip 77007

Mailing Address (if different from physical address) 7000 Cardinal Place, QRA

City Dublin State OH Zip 43017

Telephone 800-321-9549 Website www.djoglobal.com

Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Gary Middle Allen Last Opperman

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 727 N. Shepherd Dr. Suite 100

City Houston State _____ Zip _____

Telephon[redacted] Email gary.opperman@enovis.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Warsaw Community High School		1992-1996	
Address	**City**	**State**	**Zip**
1 Tiger Lane	Warsaw	IN	46580
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2012-Present	[redacted]	Cypress	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Enovis (Trilliant Surgical)			01/2014 - Present
Business Address	**City**	**State**	**Zip**
727 N. Shepherd Dr.	Houston	TX	77007
Phone	**Title**	**Number of Employed Hours**	
800-321-9549	Director, Manufacturer	6000 +	

Description of Duties

Lead manufacturing operations with a focus on medical device production, ensuring compliance with FDA regulations and ISO 13485 standards. Develop/execute strategies to enhance efficiency, quality, and scalability for device manufactu

Business Name			From - To (MM/YY – MM/YY)
Enovis (Trilliant Surgical)			05/2012- 01/2014
Business Address	**City**	**State**	**Zip**
727 N. Shepherd Dr.	Houston	TX	77007
Phone	**Title**	**Number of Employed Hours**	
800-321-9549	Director of Manufacturing	6000 +	

Description of Duties

Established and scaled a state-of-the- art manufacturing facility specializing in precision medical implants. Creating CNC programs for 5-axis mills, latches, and Swiss machines, ensuring precision and reliability in device production

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest N/A	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/09/2025
Date

I, Gary Opperman, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. GO I am at least 21 years of age;
3. GO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gary Opperman
Print Name (First, Last)

Gary Opp
Original Signature (electronic, copies or stamps not accepted)

10/09/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gary Opperman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/09/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Harris

I, Gary Opperman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/9/2025

Date

Subscribed and Sworn to before me this 9th day of October 2025

Notary Public Signature

Joshua T. Cook
My Commission Expires
5/4/2026
Notary ID
133741833

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Trilliant Surgical, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): New App

Physical Address: 727 N. Shepherd Dr. Suite 100

City: Houston State: TX Zip: 77007

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin State: OH Zip: 43017

Telephone: 800-321-9549 Website: www.djoglobal.com

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: Gary Middle: Allen Last: Opperman

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 727 N. Shepherd Dr. Suite 100

City: Houston State: TX Zip: 77007

Telephone: [redacted] Email: gary.opperman@enovis.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Warsaw Community High School		1992-1996	
Address	**City**	**State**	**Zip**
1 Tiger Lane	Warsaw	IN	46580
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2012-Present	[redacted]	Cypress	TX	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Enovis (Trilliant Surgical)			01/2014 - Present
Business Address	**City**	**State**	**Zip**
727 N. Shepherd Dr.	Houston	TX	77007
Phone	**Title**		
800-321-9549	Director, Manufacturer		

Description of Duties

Lead manufacturing operations with a focus on medical device production, ensuring compliance with FDA regulations and ISO 13485 standards. Develop/execute strategies to enhance efficiency, quality, and scalability for device manufacturing

Business Name			From - To (MM/YY – MM/YY)
Enovis (Trilliant Surgical)			05/2012- 01/2014
Business Address	**City**	**State**	**Zip**
727 N. Shepherd Dr.	Houston	TX	77007
Phone	**Title**		
800-321-9549	Director of Manufacturing		

Description of Duties

Established and scaled a state-of-the- art manufacturing facility specializing in precision medical implants. Creating CNC programs for 5-axis mills, latches, and Swiss machines, ensuring precision and reliability in device production

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Gary Oggs
Original Signature (electronic, copies or stamps not accepted)

10/09/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gary Opperman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/09/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Harris

I, Gary Opperman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/9/2025

Date

Subscribed and Sworn to before me this 9th day of October 2025

Joshua T. Cook
My Commission Expires
5/4/2026
Notary ID
133741833

Notary Public Signature

(Seal)

DJO GLOBAL

DJO, LLC

A DJO Global Company

1430 Decision Street

Vista, CA 92081-8553

T 800.321.9549

DJOglobal.com

Trilliant Surgical, LLC
727 N. Shepherd Dr.
Suite 100
Houston, TX 77007

Employee List
(New Facility)

Gary Opperman - *Director, Advanced Manufacturing Technology*
Rubi Vargas - *Distribution Manager*

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Visus Therapeutics, Inc.

Physical Address: 70 Birch Alley, Suite 240, Room 264

City: Beavercreek State: OH Zip: 45440

Mailing Address (if different from physical address): 70 Birch Alley, Suite 240, Room 264

City: Beavercreek State: OH Zip: 45440

Telephone: (937) 306-6200 Website: https://www.visustx.com/

Name of Designated Representative (DR): Timothy Grinstead

Licensing Company Email: licenses@visustx.com DR Email: licenses@visustx.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed within last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Tenpoint Therapeutics Holding Ltd

Corporation/Organization Name: Visus Therapeutics, Inc

Mailing Address: 70 Birch Alley, Suite 240, Room 264

City: Beavercreek State: OH Zip: 45440

Telephone: (937) 306-6200 Email: licenses@visustx.com

Contact Person Name: Timothy Grinstead

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Visus Therapeutics, Inc.
Facility Name

Timothy Grinstead
Print Name of Authorized Person Submitting Application

Timothy Grinstead
Original signature of Authorized Person (copies or stamps not accepted)

06/06/2025
Date

Board Use Only	Date Received: 7/2/25	Amount: $1000 CK 3965

VISUS
THERAPEUTICS

Description of Operations

Visus is a Virtual Manufacturer. Visus's products are manufactured by a Contract Manufacturer and will be distributed to Wholesalers & Specialty Distributors by their Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

The Ritedose Corporation
1135 Performance Parkway
Columbia, SC 29203
FDA EIN: 3001237796

The Ritedose Corporation
1 Technology Circle
Columbia, SC 29203
FDA EIN: 3001237796

The Ritedose Corporation manufactures Visus's product and packages finished product. At no time does The Ritedose Corporation own the product, contract with Visus's customers, invoice, nor sell a Visus product. Visus's products are not Controlled Substances.

Labeler Code:
84892

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal Health acts as Visus's Third Party Logistics (3PL) provider to manage the storage and distribution of Visus's product throughout the United States. Cardinal Health's address is:

Cardinal Health
501 Mason Rd., Ste. 200 La Vergne, Tennessee 37086

Visus's has 1 employee working on site during normal business hours.

Visus' hours of operation are TUE – FRI 12:00p – 4:00pm; Closed SAT, SUN & MON

Visus's records are stored at the 3PL

VISUS
THERAPEUTICS

Product List

PDUFA DATE: January 2026

Visus owns the Product

NDC Code	***Name***	***Dosage***	***CS Schedule***
84892–275–01	Yuvezzi	Single Use Vials	N/A

Labeler code: 84892

	A	B	C	D	E	F	G
	NDC/NHRIC Labeler	Firm Name					
00	74891	Golden Lab, LLC					
01	76605	Pecan Bayou Enterprises, LLC					
02	39386	Pilgrim's Pride Corporation					
03	84280	The Janz Corporation					
04	69933	PEARL WORLD INC.					
05	79931	Steel Supplements, Inc.					
06	73998	True Value Company, L.L.C.					
07	59448	ASP Global, LLC					
08	51609	Fitness Systems Manufacturing					
09	61444	Cambridge Isotope Laboratories, Inc.					
10	76842	Adora					
11	72893	Acrotech Biopharma LLC					
12	68452	AmSan					
13	10922	Intendis Inc					
14	73924	Zandraa					
15	74065	Ava Food Labs, Inc.					
16	72078	Mylan Institutional LLC					
17	52743	JNL Co,.Ltd.					
18	50996	Smith's Drugs fo Forest City, Inc. dba Smith Drugs					
19	84892	Visus Therapeutics, Inc.					
20	75607	Mark Andy Inc					
21	76065	Living Well Labs					

FDA Labeler verified 7/9/25 KJ

Company Information

Company Name: Visus Therapeutics, Inc.
Address: 70 Birch Alley, Suite 240, Room 264
City, State, Zip: Beavercreek, Ohio, 45440
Phone: (937) 306-6200
Website: https://www.visustx.com/
E-mail: licenses@visustx.com

FEIN: 84-3379554
State of Formation: Delaware
Date Incorporated: 10/09/2019
File Number: 7615556

Ownership Information

Visus Therapeutics, Inc. is 100% owned by Tenpoint Therapeutics Holding Ltd

Parent Company Address: London Innovation Centre, 20 Water Street 4th Floor, Office 3, London, UK, E149GG
Parent Company Phone: (937) 306-6200
Parent Company FEIN: 3001237796

Officers

Timothy Michael Grinstead, Chief Operating Officer

Melissa Bartlett Epperly, Chief Financial Officer

Benjamin Scott Bergo, Chief Executive Officer

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VISUS THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF OCTOBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VISUS THERAPEUTICS, INC." WAS INCORPORATED ON THE NINTH DAY OF OCTOBER, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7615556 8300

SR# 20254216068

Authentication: 204985411

Date: 10-08-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Ohio Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2027.

Visus Therapeutics, Inc.

70 Birch Aly Ste 240 Rm 264

Beavercrk Twp, OH 45440-1477

License Number: 0130000759

License Type: Wholesaler - Category 2

Sub-Category: VW – Virtual Wholesaler

Expiration Date: June 30, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
TIMOTHY GRINSTEAD	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

TRAVELERS

Travelers Casualty & Surety Company of America

License No. _____

RIDER

To be attached to and form part of Bond No. 108206049.

Issued on behalf of Visus Therapeutics, Inc. as Principal, and in favor of Nevada State Board of Pharmacy as Obligee.

It is agreed that:

☐ 1. The Surety hereby gives its consent to change the Name:

from: _____

to: _____

☒ 2. The Surety hereby gives its consent to change the Address:

from: 5151 California Ave., Ste 200, Irvine, CA 92617

to: 70 Birch Alley, Suite 240, Room 264, Beavercreek, OH 45440

☐ 3. The Surety hereby gives its consent to change the _____:

from: _____

to: _____

This rider shall become effective as of November 3, 2025

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated November 3, 2025.

Travelers Casualty & Surety Company of America

By: _____

James H. Savitch
Attorney-in-Fact

Accepted: Nevada State Board of Pharmacy
Obligee

By: _____

or Visus Therapeutics, Inc.
Principal

By: _____

S-4111 (8/66)

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and the Companies do hereby make, constitute and appoint **James H Savitch** of **BINGHAMTON**, **New York**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **16th** day of **February, 2024**.

SEAL SEAL SEAL

State of Connecticut

By: _____
Bryce Grissom, Senior Vice President

City of Hartford ss.

On this the **16th** day of **February, 2024**, before me personally appeared **Bryce Grissom**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

ANNA P NOWIK NOTARY PUBLIC CONNECTICUT

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **3rd** day of **November**, **2025**

SEAL SEAL SEAL

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 108206049

Application/License No. _____

Visus Therapeutics, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5151 California Ave., Ste 200, Irvine, CA 92617 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty & Surety Company of Ameria (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square, Hartford, Connecticut (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Sept. 4, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of September, 2025.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Travelers Casualty & Surety Company of Ameria

Surety Company's Representative

James H. Savitch, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Alex J. Crider
Notary Public, State of Ohio
My Commission Expires 10-18-2026

Countersigned by:

Nevada Resident Agent

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Visus Therapeutics, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 70 Birch Alley, Suite 240, Room 264

City Beavercreek State OH Zip 45440

Mailing Address (if different from physical address) 70 Birch Alley, Suite 240, Room 264

City Beavercreek State OH Zip 45440

Telephone (937) 306-6200 Website https://www.visustx.com/

Licensing Company Email licenses@visustx.com

Section 2: Personal Information

First Timothy Middle Michael Last Grinstead

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 70 Birch Alley, Suite 240, Room 264

City Beavercreek State OH Zip 45440

Telephone [redacted] Email licenses@visustx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Wright State University		(09/88 - 05-96)	
Address	**City**	**State**	**Zip**
3640 Colonel Glenn Highway	Dayton	OH	45435
Diploma/Degree obtained, if any			
BS/MS			

School Name		From - To (MM/YY – MM/YY)	
Beavercreek High School		(08/85 - 06/88)	
Address	**City**	**State**	**Zip**
2660 Dayton Xenia Rd	Dayton	OH	45434
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
(04/23 - Present)	[redacted]	Xenia	OH	[redacted]
From - To (MM/YY – MM/YY		City	State	
(02/03 - 04/23)		Beavercreek	OH	
From - To (MM/YY – MM/YY		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Visus Therapeutics, Inc.			(06/21 - Present)
Business Address	**City**	**State**	**Zip**
70 Birch Alley, Suite 240, Room 264	Beavercreek	OH	45440
Phone	**Title**	**Number of Employed Hours**	
(937) 306-6200	COO	7,500	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Alkermes			(10/18 - 05/21)
Business Address	**City**	**State**	**Zip**
265 Olinger Circle	Wilmington	OH	45177
Phone	**Title**	**Number of Employed Hours**	
(937) 382-5642	VP & GM	4,960	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Alkermes			(04/17 - 10/18)
Business Address	**City**	**State**	**Zip**
265 Olinger Circle	Wilmington	OH	45177
Phone	**Title**	**Number of Employed Hours**	
(937) 382-5642	VP of Manufacturing	2,880	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Iveric Bio			(06/16 - 03/17)
Business Address	**City**	**State**	**Zip**
5555 Airport Blvd, Suite 100	Boulder	CO	80301
Phone	**Title**	**Number of Employed Hours**	
	VP of Commercial Manufacturing	1,440	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Timothy Grinstead, **certify that as the designated representative for**

Visus Therapeutics, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TG I am at least 21 years of age;
3. TG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Timothy Grinstead

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/06/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Timothy Grinstead

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/06/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Greene

I, TIMOTHY GRINSTEAD, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/06/2025

Date

Subscribed and Sworn to before me this 6th day of June, 2025.

Notary Public Signature

Carson J. Woods
Notary Public, State of Ohio
My Commission Expires 11-13-2028
(Seal)

Contact

tim.grinstead@visustx.com

www.linkedin.com/in/tim-grinstead-120b5017 (LinkedIn)

Top Skills

Pharmaceutical Industry
Quality Assurance
Quality Control

Tim Grinstead

Chief Operating Officer at Visus Therapeutics, Inc.
Dayton, Ohio, United States

Summary

Pharmaceutical C-Suite Executive with a diverse technical and operational background . Experience working in the fields of QA, QC, Manufacturing, Supply Chain, IT, Legal and Engineering. Technical experience running sites that produce commercial and clinical supplies for sterile, biologics, solid oral dose and liquid products. Multiple, successful implementations of a unique operational excellence system that employs behavioral based elements as well as lean manufacturing concepts and tools. Formal education in chemistry including an extensive background in organic synthesis and analytical chemistry.

Experience

Visus Therapeutics, Inc.
Chief Operating Officer
June 2021 - Present (3 years 5 months)
Seattle, Washington, United States

Operational leader and senior executive for a clinical-stage company developing innovative medicines to improve vision for people around the world. The lead program is focused on developing the world's first presbyopia-correcting eye drop with the potential to last a minimum of eight hours. Providing a broad range of leadership skills to progress the lead compound, build infrastructure and implement systems to aid in the overall growth of the team members, the company and corporate values. Areas of responsibility include CMC, Quality, IT, Legal and Supply Chain. Attend Board of Director meetings and responsible for preparing the Board of Director meeting content and providing relevant Operational updates.

Alkermes
4 years 2 months

Vice President and General Manager
October 2018 - May 2021 (2 years 8 months)
Wilmington, Ohio

Site leader for a diverse biotechnology company that manufactures long acting injectable products, solid oral dosage forms and biotechnology clinical supplies. Alkermes specializes in CNS indications using proprietary technology platforms and as well as company developed API's. Site consisted of over 500 employees and was responsible for manufacturing the products that accounted for a major portion of the companies revenues. Full P&L responsibility of the site.

Vice President of Manufacturing
April 2017 - October 2018 (1 year 7 months)
Wilmington, Ohio

Iveric Bio, An Astellas Company
Vice President of Commercial Manufacturing
June 2016 - March 2017 (10 months)
Boulder, CO

Commercial manufacturing leader for a biotechnology company focused on diseases of the eye. Responsibilities include oversight of the drug substance commercial manufacturing process that employed nucleotide chemistry as well as the sterile drug product filling and packaging functions.

Mane
Vice President of Operations
May 2014 - June 2016 (2 years 2 months)

Vice President of Operations overseeing multiple sites for Mane, an international flavor and fragrance company. The sites consisted of over 600 employees and was the primary research and manufacturing facility for Mane in North America.

Adare Pharma Solutions
Senior Director, Manufacturing Operations, North America
August 1993 - May 2014 (20 years 10 months)
Vandalia, Ohio

Managed all manufacturing operations within North America for Adare Pharmaceuticals including plants in Vandalia, OH and Montreal, Canada. The site specialized in proprietary drug delivery technologies and engaged in both internal projects and CDMO activities.

Wright-Patterson Air Force Base
Research Chemist
August 1991 - August 1993 (2 years 1 month)

Synthesis of Non Linear Organic Compounds

Education

Wright State University

BS/MS, Chemistry · (1988 - 1996)

Employee List

Legal first name	Legal last name
Yvette	Aldrich
Lana	Aryan
Benjamin	Bergo
Robert	Boxeth
James	Burke
Matthew	Chang
Telecia	Cooper
John	Cummings
Esther	Cuno
Cam	Dang
Sarah	Ennis
Andrew	Firpo
Damon	Fletcher
Timothy	Grinstead
Patrick	Hughes
Joscelyn	Jones
Craig	Kramer
Dell	Larned
Kim	Le
Steven	Lesiak
Katherine	Manzanera
Mia	Merino
Lee	Merrill
Mark	Paciolla
Mitchell	Penney
Rhett	Schiffman
Emily	Schmitt
Robert	Shook
Lisa	Simpson
David	Toll
Sarah	Tuller
Julia	Williams
Zohra	Womack
Aqsa	Zahid

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03736	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: COUPLER LLC

Physical Address: 1140 MCDERMOTT DRIVE, SUITE 104

City: WEST CHESTER State: PA Zip: 19380

Mailing Address (if different from physical address): SAME AS PHYSICAL ADDRESS

City: State: Zip:

Telephone: 215-394-5995 Website: WWW.COUPLERRX.COM

Name of Designated Representative (DR): JEFFREY JONES

Licensing Company Email: GHUNT@POLARISRX.COM DR Email: JJONES@COUPLERRX.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	■ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: CORRECTIONAL FACILITIES NURSING HOMES		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	MINNEAPOLIS	RAMSEY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
265279		MINNESOTA BOARD OF PHARMACY		
Reason/Charge				
PHARMACY WAS ALLOWING REMOTE ORDER ENTRY				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
PLEASE SEE ATTACHED			HEARING	
Name of Business/Industry/Entity				
POLARIS PHARMACY SERVICES OF MINNESOTA, LLC				

Provide explanation below:

PLEASE SEE ATTACHED

Original Signature (electronic, copies or stamps not accepted)

12/4/25
Date

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND
CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board REPRIMANDS Licensee and imposes a CIVIL PENALTY in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following CONDITION on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board REPRIMANDS Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/28/2023	9/19/2024	MO	JEFFERSON CITY	COLE
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		MISSOURI BOARD OF PHARMACY		
Reason/Charge				
DISTRIBUTED MULTIPLE DRUGS WITH MISCONDUCT WHILE LICENSE NOT IN GOOD STANDING WITH MISSOURI LICENSE				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
PLEASE SEE ATTACHED				
Name of Business/Industry/Entity				
COUPLER LLC				

Provide explanation below:

PLEASE SEE ATTACHED

Original Signature (electronic, copies or stamps not accepted)

12/4/25
Date

COUPLER

Statement Regarding Disciplinary Action

Coupler Enterprises Inc was acquired by Coupler LLC in March 2023. At the time of the acquisition, Coupler Enterprises was licensed in multiple states and a change of ownership was completed for each license held by the previous owner. Coupler LLC made a good faith effort to complete all the change of ownership applications for all states licensed by Coupler Enterprises Inc.

In April 2024, Coupler LLC relocated to 1140 McDermott Drive, Suite 104, West Chester, PA 19380. Soon after the move, Coupler LLC prepared the relocation application for the Missouri Board of Pharmacy and discovered that the change of ownership was not completed. Coupler LLC submitted both the change of ownership and change of location applications to the Board. Due to staff turnover after the acquisition and the transition in ownership, some of our internal processes became sluggish, leading to clerical errors caused by new hires.

The Missouri Board of Pharmacy issued Coupler LLC permit # 2024036874 on 09/10/2024 and placed the permit on probation for two (2) years.

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
9314 8699 0430 0126 9569 71

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

October 2, 2024

Brian Fries, MIC
Coupler LLC
1140 Mcdermott Dr.
Ste. 104
West Chester, PA 19380

Dear Mr. Gries:

Enclosed is a copy of the fully executed **ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING COUPLER LLC A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION** regarding your Missouri pharmacy permit #2024036874. The Order is effective September 10, 2024.

Enclosed are two copies of our Pharmacy and Drug Distributor Report of Discipline Compliance form for use in submitting the six-month reports required by the Agreement. The first report will be due **January 1, 2025**, and each January and July following through the ending date of probation. This form may be copied as needed for future use, and is also available on our website at www.pr.mo.gov/pharmacists, click Applications and Forms, under Miscellaneous.

You should review each term of this Agreement and comply with the requirements as set forth. Compliance with this Agreement is your responsibility; reminders will not be sent from this office. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

Sincerely,

JENNIFER BOEHM
ADMINISTRATIVE COORDINATOR

Enclosure

cc: David Rombro, CERTIFIED MAIL TRACKING NO 9314 8699 0430 0126 9574 28
Jackie Le Via E-mail JLe@polarisrx.com

BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:	)
	)
COUPLER LLC	)
1140 McDermott Dr, Suite 104	)
West Chester, PA 19830	)

ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING COUPLER LLC A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2024036874, to COUPLER LLC pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, COUPLER LLC may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to COUPLER LLC. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of COUPLER LLC's drug distributor license. Should COUPLER LLC file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. COUPLER LLC operates a drug distributorship at 1140 McDermott Dr., Suite 104, West Chester, Pennsylvania. COUPLER LLC distributed multiple drugs into Missouri from November 28, 2023 through May 17, 2024 without holding a current Missouri license.

3. COUPLER LLC filed an application for a drug distributor license with the Board for the McDermott facility on or about May 17, 2024. The license issued pursuant to this Order is in response to that application.

4. Section 338.333, RSMo prohibits acting as a drug distributor without first obtaining a license to do so from the Missouri Board of Pharmacy.

5. Likewise, §338.337 and 20 CSR 2220-5.050(2) specifically require an out-of-state drug distributor doing business in this state to obtain a license.

6. COUPLER LLC's conduct as alleged above is cause for the Board to deny COUPLER LLC licensure as a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

> 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section.
>
> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling ay person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

7. Section 324.038.1, RSMo, provides in pertinent part:

1. Whenever a board within or assigned to the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

ORDER

8. Based on the foregoing, it is the ORDER of the Missouri Board of Pharmacy that, in lieu of denying licensure as a drug distributor, the Board hereby issues COUPLER LLC's drug distributor license number 2024036874 subject to PROBATION for a period of **TWO YEARS**. This Order shall become effective on the date issued. The terms of probation shall be:

A. COUPLER LLC shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

B. COUPLER LLC shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If, after disciplinary sanctions have been imposed, COUPLER LLC fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

D. COUPLER LLC shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its

disciplinary order.

E. COUPLER LLC agrees that it will make itself available for inspection by inspectors employed by the Missouri Board of Pharmacy between January 1 and December 31 of each year it is under discipline. This also includes the beginning and ending years of the discipline. The Respondent shall reimburse the Board for travel expenses and meals incurred to facilitate these inspections including, but not limited to, airfare, lodging, shuttle, and transportation expenses within seven (7) days of being provided a notice and valid receipts for said expenses. Travel expenses and meals shall be governed by the recognized Missouri Office of Administration guidelines for state employee travel.

F. COUPLER LLC shall not serve as an intern training facility for intern pharmacists.

G. COUPLER LLC shall make a representative available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. COUPLER LLC will be notified and given sufficient time to arrange these meetings.

H. COUPLER LLC's failure to comply with any condition of discipline set forth herein constitutes a violation of this Order.

9. Upon the expiration of said probation, COUPLER LLC's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that COUPLER LLC has violated any term or condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline COUPLER LLC

10. No order shall be entered by the Board pursuant to the preceding

paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

11. If the Board determines that COUPLER LLC has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Order occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Order has occurred.

12. The Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

SO ORDERED this 10th day of September 2024.

BOARD SEAL

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
MISSOURI BOARD OF PHARMACY

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: CENCORA (FORMERLY AMERISOURCE BERGEN)
Address: 1 WEST FIRST AVE City: CONSHOHOCKEN State: PA Zip: 19428
Name: JAMSRX WHOLESALE DISTRIBUTION LLC
Address: 4811 LYONS TECHNOLOGY City: COCONUT CREEK State: FL Zip: 33073
Name: BLUPAX PHARMA
Address: 160 RARITAN CENTER PWKY, UNIT 1 City: EDISON State: NJ Zip: 08837
Name: KEYSOURCE MEDICAL
Address: 7820 PALACE DR City: CINCINNATI State: OH Zip: 45249

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PENNSYLVANIA / COUPLER LLC
Parent Company (if any): POLARIS PHARMACY SERVICES OF WARRINGTON, LLC
Corporation/Organization Name: COUPLER LLC
Mailing Address: 1140 MCDERMOTT DRIVE, SUITE 104
City: WEST CHESTER State: PA Zip: 19380
Telephone: 215-394-5995 Email: GHUNT@POLARISRX.COM
Contact Person Name: GINA HUNT

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Forms/Application_Packet_Instructions_2015.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

COUPLER LLC

Facility Name

DAVID ROMBRO (CEO)

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/4/25

Date

Board Use Only	Date Received: 12/8/25	Amount: $1000 ck. 1064

Accredited Drug Distributors

Find an Accredited Drug Distributor

<<Previous 1 2 3 4 5 6 Next >>

Name	Address	Accreditation Date
Catalent Pharma Solutions, LLC	3031 Red Lion Road Philadelphia, PA 19114	11/23/23
Catalent Pharma Solutions, LLC	10360 Drummond Road Philadelphia, PA 19154	01/26/24
Central Admixture Pharmacy Services, Inc	6580 Snowdrift Road, Ste 100 Allentown, PA 18106	04/10/23
Central Admixture Pharmacy Services, Inc. (CAPS)	6845 Snowdrift Road, Ste 100 Allentown, PA 18106	01/23/24
Chewy Wholesale, LLC	170 Research Dr Pittston, PA 18640	06/23/25
Coupler, LLC	1140 McDermott Dr, Ste 104 West Chester, PA 19380	05/15/25
Covetrus North America, LLC dba Covetrus North America	1499 Zeager Rd, Ste 5 Elizabethtown, PA 17022	12/06/23
Diamond Drugs, Inc dba Diamond Pharmacy Services	665 Holter Dr Indiana, PA 15701	09/14/24
Digestive Care Inc.	1120 Win Drive Bethlehem, PA 18017	04/01/25
Dixon Share, LLC dba R&S Northeast, LLC	10049 Sandmeyer Lane Philadelphia, PA 19116	02/05/25

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Contact

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NABP ACCREDITED
DRUG DISTRIBUTOR

Coupler, LLC

located at

1140 McDermott Dr, Ste 104, West Chester, PA 19380

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Coupler**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Coupler LLC	3003734940	119003108	REPACK;	1140 McDermott Drive, Suite 104, West Chester, Pennsylvania (PA) 19380, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Monday, Jan 12, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Coupler LLC

Officer, Ownership & Manager Detail

1140 McDermott Drive, Suite 104
West Chester, PA 19380
FEIN: 92-3571836

Officer Name	DOB	SSN
David Rombro (CEO) [redacted] Email: drombro@polarisrx.com	[redacted]	
Robert Meyer (CFO) [redacted] Email: rmeyer@polarisrx.com		
Steven Baker (COO) [redacted] Email: sbaker@polarisrx.com		

Ownership

Coupler LLC

which is owned by: Polaris Pharmacy Services of Warrington LLC (100%)

which is owned by: Polaris Pharmacy Services of Philadelphia LLC (100%)

which is owned by: Polaris Pharmacy Services LLC (100%)

***all have same officers**

Polaris Pharmacy Services, LLC

2900 NW 60th Street
Ft Lauderdale, FL 33309

FEIN: 47-4098540
Owned by: Da Pharmacy Guys, LLC (19.58%)
Enhanced Medical Services (19.53%)
EJJ Pharma, LLC (20.24%)
PPGRX North Carolina, LLC (40.65%)

Managers: David W. Rombro, Daniel Galbut, Harold Sussman
Officers: David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

***No one person owns more than 10%**

Managers

David Rombro

[redacted]

Email: drombro@polarisrx.com

Daniel Galbut

[redacted]

Harold Sussman

[redacted]

Email: hsussman@kochngroup.com

Responsible Agent for Board Communication
Gina Hunt

[redacted]

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	Coupler LLC
Request Type:	Subsistence Certificate
Request No.:	053790119
Receipt No.:	001564893
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	March 31, 2023
Status:	Active

Issuance Date: April 01, 2025
File No.: 0012930554

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

Coupler LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

Certificate of Registration

Certificate No. 1000004407
(A certificate starting with a number 4, 5 or 6 does not permit the possession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
2525 N. 7th Street
Suite 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:

Manufacturer (Prescription)

COUPLER LLC
1140 MCDERMOTT DRIVE
SUITE 104
WEST CHESTER, PA 19380

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: May 23, 2023
Expiration Date: The Last Day of June, 2026

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Certificate of Licensure

Certificate No. 8000003149
(A certificate starting with a number 4, 5 or 6 does not permit the possession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
2525 N. 7th Street
Suite 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:

Wholesaler/Distributor

COUPLER LLC
1140 MCDERMOTT DRIVE
SUITE 104
WEST CHESTER, PA 19380

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: May 23, 2023
Expiration Date: The Last Day of June, 2026

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0659574	08-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	MANUFACTURER	07-08-2025

COUPLER, LLC
1140 MCDERMOTT DR STE 104
WEST CHESTER, PA 193804043

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0659574	08-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	MANUFACTURER	07-08-2025

COUPLER, LLC
1140 MCDERMOTT DR STE 104
WEST CHESTER, PA 193804043

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0659574	08-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	MANUFACTURER	07-08-2025

COUPLER, LLC
1140 MCDERMOTT DR STE 104
WEST CHESTER, PA 193804043

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2100 4000

COUPLER

Clarification Regarding Personal History Record Application for Coupler LLC

There is no individual owning more than 10% of the business, therefore a personal history record application was not included with this change of ownership application.

Coupler LLC
1140 McDermott Drive, Suite 104 | West Chester, PA 19380 | p 215-394-5995 | f 267-282-5906

COUPLER LLC

Bond Information for Change of Ownership Application

Coupler LLC has maintained a bond in compliance with Board requirements. The new owner is currently in the process of obtaining a title change on the existing bond to reflect the updated company ownership. Documentation of the revised bond will be submitted to the Board upon completion.

Coupler LLC
1140 McDermott Drive, Suite 104 | West Chester, PA 19380 | p 215-394-5995 | f 267-282-5906

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 108397737

Application/License No. _____

POLARIS PHARMACY SERVICES OF WARRINGTON, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1140 MCDERMOTT DRIVE, SUITE #104, WEST CHESTER, PA 19380 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CONNECTICUT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square, Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 01, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11 day of December, 2025.

APPLICANT/PRINCIPAL

POLARIS PHARMACY SERVICES OF WARRINGTON, LLC

Authorized Representative

SURETY COMPANY

Travelers Casualty and Surety Company of America

SEAL

Surety Company's Representative

Patrick T. Battle, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Kayla Delmadino
Witness

Jeanette Cabrera
Witness

Countersigned by:

n/a
Nevada Resident Agent

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and the Companies do hereby make, constitute and appoint **PATRICK T BATTLE** of **MIAMI LAKES**, **Florida**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **16th** day of **February, 2024**.

SEAL SEAL SEAL

State of Connecticut

By: _____
Bryce Grissom, Senior Vice President

City of Hartford ss.

On this the **16th** day of **February, 2024**, before me personally appeared **Bryce Grissom**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

NOTARY PUBLIC CONNECTICUT

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **11th** day of **December**, **2025**.

SEAL SEAL SEAL

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler COUPLER LLC

Pharmacy/Wholesaler License # (if applicable) WH03736 (CHANGE OF OWNERSHIP PENDING)

Physical Address 1140 MCDERMOTT DRIVE, SUITE 104

City WEST CHESTER State PA Zip 19380

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 215-394-5995 Website WWW.COUPLERRX.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First JEFFREY Middle PATRICK Last JONES

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 1140 MCDERMOTT DRIVE, SUITE 104

City WEST CHESTER State PA Zip 19380

Telephon[redacted] Email JJONES@COUPLERRX.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
TEMPLE UNIVERSITY		09/99 - 05/01	
Address	City	State	Zip
1810 N 13TH STREET	PHILADELPHIA	PA	19122
Diploma/Degree obtained, if any			
BS TOURISM & HOSPITALITY MANAGEMENT; MAJOR: SPORT & RECREATION MANAGEMENT			

School Name		From - To (MM/YY – MM/YY)	
WIDENER UNIVERSITY		09/96 - 05/99	
Address	City	State	Zip
1 UNIVERSITY PLACE	CHESTER	PA	19013
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
MONSIGNOR BONNER HIGH SCHOOL		09/92 - 06/96	
Address	City	State	Zip
406 N LANSDOWNE AVE	DREXEL HILL	PA	19026
Diploma/Degree obtained, if any			
HS DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20 - CURRENT	[redacted]	GLEN MILLS	PA	[redacted]
02/12 - 06/20	[redacted]	SPRINGFIELD	PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Coupler LLC			12/24 - CURRENT	
Business Address		**City**	**State**	**Zip**
1140 McDermott Drive, Suite 104		West Chester	PA	19380
Phone	**Title**		**Number of Employed Hours**	
626.626.9429, ext-1038	Operations Manager		2080	
Description of Duties				
Responsible for daily operation in managing facility which includes leading staff, ensuring staff is trained and working in compliance with cGMP/FDA/DEA regulations and Coupler SOPs. Serve as site Designated Responsible person.				

Business Name			From - To (MM/YY – MM/YY)	
International Flavors and Fragrances			04/23 - 09/24	
Business Address		**City**	**State**	**Zip**
1301 Ogletown Road		Newark	DE	19711
Phone	**Title**		**Number of Employed Hours**	
302.451.0100	Operations Manager		3,000	
Description of Duties				
Responsible for overall Production Manufacturing and Logistics operations (Union & Non-union) (Supervisors, Operators, Process Engineering, Process Automation, Warehouse) in cGMP, FDA governed facility.				

Business Name			From - To (MM/YY – MM/YY)	
Johnson Matthey Pharmaceutical Materials / Veranova LLC			11/04 - 03/23	
Business Address		**City**	**State**	**Zip**
2003 Nolte Drive		West Deptford	NJ	08066
Phone	**Title**		**Number of Employed Hours**	
856.384.7081	Production Manager		38,000 +	
Description of Duties				
Responsible for the overall operations of API production (FDA/DEA) in all areas of Safety, Quality, Delivery, Cost, People. Manage budget, track/report metrics, inventory transactions, deviations, change control, SOPs, Training, Continuous Imp.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
JOHNSON MATTHEY PHARMACEUTICAL MATERIALS / VERANOVA LLC			11/04 - 03/23	
Business Address		City	State	Zip
2003 NOLTE DRIVE		WEST DEPTFORD	NJ	08066
Phone	Title		Number of Employed Hours	
856-384-7081	PRODUCTION MANAGER		38,000+	
Description of Duties				
RESPONSIBLE FOR THE OVERALL OPERATIONS OF PRODUCTION (FDA/DEA) IN ALL AREAS OF SAFETY, QUALITY, DELIVERY, COST, PEOPLE, MANAGE BUDGET, TRACK/REPORT METRICS, INVENTORY TRANSACTIONS, DEVIATIONS, CHANGE CONTROL, SOPs, TRAINING, CI.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, JEFFREY PATRICK JONES, **certify that as the designated representative for**

COUPLER LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JJ I am at least 21 years of age;
3. JJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JEFFREY JONES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

26 NOV 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JEFFREY JONES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

26 Nov 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Chester

I, Jeffrey P. Jones, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

26 Nov 2025

Date

Subscribed and Sworn to before me this 26th day of November 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Sarah A. Young, Notary Public
Chester County
My Commission Expires July 27, 2029
Commission Number 1250320

(Seal)

COUPLER

List of Employees of Coupler LLC

Employee Name	Title
Jones, Jeffrey P	Operations Manager/Designated Representative
Kerr, Chelsea	Workflow Lead
Miroddi, Sarah	Quality Assurance Technician
Hodges, Kimberly Anne	Fill Technician
Nellimoottil, Hima K	Fill Technician
Widger, Denise E	Fill Technician
Weatherill, Jessica	Shipper/Receiver

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: A2A Alliance Pharmaceuticals, LLC

Physical Address: 75 Raines Drive Suite B

City: Franklin State: KY Zip: 42134

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 844-900-6001 Website: https://www.a2aalliancepharma.us/

Name of Designated Representative (DR): Rondal Turner

Licensing Company Email: licenses@a2apharmgov.com DR Email: rondal.turner@a2aalliancepharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: Non prescription drugs	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Govt. Entities (VA)		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	X	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	X	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1989	N/A	KY	Lexington	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	N/A

Reason/Charge
DUI - Fine and license suspension for 30 days, not considered a felony

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
Douglas Taulbee

Provide explanation below:

Douglas Taulbee received a DUI in Lexington KY in 1989. Fine and license was suspended for 30 days. He has had no other arrests or violations since then. It was not considered a felony.

Douglas A Taulbee

Original Signature (electronic, copies or stamps not accepted)

6/5/25

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge
A2A Alliance has voluntarily surrendered licenses.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please see attached for surrender list*

Original Signature (electronic, copies or stamps not accepted)

June 10, 2025
Date

A2A Alliance Pharmaceuticals, LLC

75 Raines Drive, Suite B

Franklin, KY 42134

FEIN: 85-1797376

Surrendered/Closed License List

State	Status	License Type	License #	Date of Action	Location	Reason
AL	Surrendered	Wholesale - Virtual	196239	3.3.2025	Bowling Green, KY	Relocated and not virtual anymore, received a new AL license
WA	Surrendered	Wholesaler	PHWH.FX.61250716	3.13.25	Bowling Green, KY	State closed and issued new license number for the new location
OK	Closed	Wholesale Distributor	88-W-7195	3.14.25	Bowling Green, KY	State closed and issued new license number for the new location
OH	Surrendered	Wholesale Distributor	0130000429	6.23.25	Bowling Green, KY	State closed and issued new license number for the new location
UT	Surrendered	Wholesaler - Virtual	12649919-1710	3.2025	Bowling Green, KY	Relocated and not virtual anymore, applied for a new UT license

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: A2A Integrated Pharmaceuticals, LLC

Address: 75 Raines Drive Suite A City: Franklin State: KY Zip: 42134

Name: Yaral Pharma Inc

Address: 8 Campus Dr Suite 201A City: Parsippany State: NJ Zip: 07054

Name: Riviera Pharmaceuticals, Inc.

Address: 16100 SW Market St City: Indiantown State: FL Zip: 34956

Name: Long Grove Pharmaceuticals

Address: 9450 W Bryn Mawr Ave. Suite 200 City: Rosemont State: IL Zip: 60018

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Kentucky

Parent Company (if any):

Corporation/Organization Name: A2A Alliance Pharmaceuticals, LLC

Mailing Address: 75 Raines Drive Suite B

City: Franklin State: KY Zip: 42134

Telephone: 844-900-6001 Email: licenses@a2apharmgov.com

Contact Person Name: Rondal Turner

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

A2A Alliance Pharmaceuticals, LLC

Facility Name

Rondal Turner

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

June 10, 2025

Date

Board Use Only	Date Received: 7/2/25	Amount: 4,000-CK 010034

A2A Alliance Pharmaceuticals, LLC

75 Raines Drive, Suite B

Franklin, KY 42134

FEIN: 85-1797376

Officer Information

Jack Downing R. Ph – VP of Pharmaceutical Strategy

Residence Address: [redacted]

Social Security Number (last 4 digits): [redacted]

Date of Birth: [redacted]

Ty Downing – VP of Distribution

Residence Address: [redacted]

Social Security Number (last 4 digits) [redacted]

Date of Birth [redacted]

Douglas Taulbee – Chief Financial Officer

Residence Address: [redacted]

Social Security Number (last 4 digits): [redacted]

Date of Birth: [redacted]

Rondal Turner, COL (retired) – President + CEO

Residence Address: [redacted]

Social Security Number (last 4 digits): [redacted]

Date of Birth: [redacted]

A2A Alliance Pharmaceuticals, LLC
75 Raines Drive, Ste B
Franklin, KY 42134
FEIN: 85-1797376

Ownership Information

KODA Ventures, LLC P.O. Box 1487 Franklin, KY 42134 FEIN: 92-3413225 4% Ownership	**Jack Downing, R.Ph** 16.875 % Ownership	**Ty Downing** 16.875% Ownership	**Douglas Taulbee** 11.25% Ownership	**Rondal Turner, COL (Retired)** 51% Ownership

Jack Downing, R. Ph
Title: VP of Pharmaceutical Strategy
Business Address: 5261 Nashville Rd. Ste A, Bowling Green, KY 42101
Residence Address: [redacted]
Date of Birth [redacted]
Phone [redacted]

Ty Downing
Title: VP of Distribution
Business Address: 5261 Nashville Rd. Ste A, Bowling Green, KY 42101
Residence Address: [redacted]
Date of Birth [redacted]
Phone [redacted]

Douglas Taulbee
Title: CFO
Business Address: 5261 Nashville Rd. Ste A, Bowling Green, KY 42101
Residence Address: [redacted]
Date of Birth [redacted]
Phone [redacted]

Rondal Turner, COL (Retired)
Title: President and CEO
Business Address: 5261 Nashville Rd. Ste A, Bowling Green, KY 42101
Residence Address [redacted]
Date of Birth [redacted]
Phone: [redacted]

KODA Ventures, LLC
P.O. Box 1487
Franklin, KY 42134
FEIN: 92-3413225

KODA Ventures, LLC Ownership Information

Brian Kelley-Partner

50% Ownership of KODA Ventures, LLC

Residence [redacted]

Date of Bi

Social Sec

David Carver-Partner

50% Ownership of KODA Ventures, LLC

Residence [redacted]

Date of Bir

Social Secu

Commonwealth of Kentucky
Michael G. Adams, Secretary of State

Michael G. Adams
Secretary of State
P. O. Box 718
Frankfort, KY 40602-0718
(502) 564-3490
http://www.sos.ky.gov

Certificate of Existence

Authentication number: 330223
Visit https://web.sos.ky.gov/ftshow/certvalidate.aspx to authenticate this certificate.

I, Michael G. Adams, Secretary of State of the Commonwealth of Kentucky, do hereby certify that according to the records in the Office of the Secretary of State,

A2A Alliance Pharmaceuticals, LLC

A2A Alliance Pharmaceuticals, LLC is a limited liability company duly organized and existing under KRS Chapter 14A and KRS Chapter 275, whose date of organization is July 7, 2020 and whose period of duration is perpetual.

I further certify that all fees and penalties owed to the Secretary of State have been paid; that articles of dissolution have not been filed; and that the most recent annual report required by KRS 14A.6-010 has been delivered to the Secretary of State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal at Frankfort, Kentucky, this 10th day of March, 2025, in the 233rd year of the Commonwealth.

COMMONWEALTH OF KENTUCKY
OFFICE OF SECRETARY OF STATE

Michael G. Adams
Secretary of State
Commonwealth of Kentucky
330223/1102950

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Wholesaler

NUMBER: W04440

PIC: Rondal Turner

EFFECTIVE DATE: 08/27/2020

EXPIRATION DATE: 09/30/2025

Issued to:

A2a Alliance Pharmaceuticals Llc

75 Raines Drive
Suite B
Franklin, KY 42134

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 5340865

Application/License No. _____

A2A Alliance Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 75 Raines Drive Suite B, Franklin, KY 42134 (Address of Applicant/Principal), as PRINCIPAL, and SureTec Insurance Company (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2103 CityWest Blvd., Ste. 1300, Houston, TX 77042-2832 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of One Hundred Thousand Dollars and Zero Cents DOLLARS ($ 100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 16, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions: Bond No. 5340865

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of May, 2025.

APPLICANT/PRINCIPAL
A2A Alliance Pharmaceuticals, LLC

Authorized Representative

SURETY COMPANY
SureTec Insurance Company

Surety Company's Representative

Melissa Propst, Attorney-in-fact
print name

MICHAEL ANTHONY MCGUIRE
NOTARY PUBLIC
Comm. # KYNP73383
COMMISSION EXPIRES 8/2/2027
COMMONWEALTH OF KENTUCKY

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

POA #: 5340865

SureTec Insurance Company
LIMITED POWER OF ATTORNEY

Know All Men by These Presents, That SURETEC INSURANCE COMPANY (the "Company"), a corporation duly organized and existing under the laws of the State of Texas, and having its principal office in Houston, Harris County, Texas, does by these presents make, constitute and appoint

Melissa Propst

its true and lawful Attorney-in-fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings or other instruments or contracts of suretyship to include waivers to the conditions of contracts and consents of surety for:

A2A Alliance Pharmaceuticals, LLC (Principal)

Nevada State Board of Pharmacy (Obligee)

$100,000.00 (Penalty Amount)

and to bind the Company thereby as fully and to the same extent as if such bond were signed by the President, sealed with the corporate seal of the Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolutions of the Board of Directors of the SureTec Insurance Company:

Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached. *(Adopted at a meeting held on 20th of April, 1999.)*

In Witness Whereof, SURETEC INSURANCE COMPANY has caused these presents to be signed by its President, and its corporate seal to be hereto affixed this 3rd day of February, A.D. 2023.

SURETEC INSURANCE COMPANY

By: _____
Michael C. Keimig, President

State of Texas ss:
County of Harris

On this 3rd day of February, A.D. 2023 before me personally came Michael C. Keimig, to me known, who, being by me duly sworn, did depose and say, that he resides in Houston, Texas, that he is President of SURETEC INSURANCE COMPANY, the company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said Company; and that he signed his name thereto by like order.

TANYA SNEED
Notary Public State of Texas
Commission # 128571231
Commission Expires 03/30/2027

_____
Tanya Sneed, Notary Public
My commission expires March 30, 2027

I, M. Brent Beaty, Assistant Secretary of SURETEC INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Company, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

Given under my hand and the seal of said Company at Houston, Texas this 16th day of May, 2025 A.D.

_____
M. Brent Beaty, Assistant Secretary

Any instrument issued in excess of the penalty stated above is totally void and without any validity.
For verification of the authority of this power, contact bondverification@marketa.com

POASIC01 v1

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler A2A Alliance Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 844-900-6001 Website https://www.a2aalliancepharma.us/

Licensing Company Email licenses@a2apharmgov.com

Section 2: Personal Information

First Rondal Middle Lee Last Turner

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Telephone 844-900-6001 Email licenses@a2apharmgov.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
United States Army War College		2009 - 2010	
Address	**City**	**State**	**Zip**
651 Wright Ave	Carlisle	PA	17013
Diploma/Degree obtained, if any			
Masters Degree of Strategic Studuies			
School Name		From - To (MM/YY – MM/YY)	
Kentucky State University		1993-1994	
Address	**City**	**State**	**Zip**
400 E Main St.	Frankfort	KY	40601
Diploma/Degree obtained, if any			
Masters Degree in Public Administration			
School Name		From - To (MM/YY – MM/YY)	
Western Kentucky University		1981-1985	
Address	**City**	**State**	**Zip**
1906 College Heights Blvd	Bowling Green	KY	42101
Diploma/Degree obtained, if any			
Bachelors of Science			
School Name		From - To (MM/YY – MM/YY)	
Gamaliel High School		1978-1981	
Address	**City**	**State**	**Zip**
320 W Main St	Gamaliel	KY	42140
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/13 - Present	[redacted]	Scottsville	KY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
A2A Alliance Pharmaceuticals, LLC			July 2020 - Present
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite B	Franklin	KY	42134
Phone	**Title**	**Number of Employed Hours**	
844-900-6001	President + CEO	10,480	

Description of Duties
Turner manages the strategic infrastructure and foundation for A2A Alliance Pharmaceuticals to uphold the promise to deliver safe, effective and affordable FDA-approved pharmaceuticals and other medical related products to meet the customers' needs and ensure that patients and veterans have access to high-quality medicines when they need it.

Business Name			From - To (MM/YY – MM/YY)
A2A Integrated Pharmaceuticals, LLC			Dec 2021 - Present
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite A	Franklin	KY	42134
Phone	**Title**	**Number of Employed Hours**	
800-380-6709	Director Of Government Strategies	7,040	

Description of Duties
Involved in the oversight of the activities e.g. private label repackaging and distribution of drug products.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	X	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
A2A Alliance has surrendered multiple licenses for various reasons.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached for surrendered licenses list*

Original Signature (electronic, copies or stamps not accepted)

June 10, 2025
Date

A2A Alliance Pharmaceuticals, LLC

75 Raines Drive, Suite B

Franklin, KY 42134

FEIN: 85-1797376

Surrendered/Closed License List

State	Status	License Type	License #	Date of Action	Location	Reason
AL	Surrendered	Wholesale - Virtual	196239	3.3.2025	Bowling Green, KY	Relocated and not virtual anymore, received a new AL license
WA	Surrendered	Wholesaler	PHWH.FX.61250716	3.13.25	Bowling Green, KY	State closed and issued new license number for the new location
OK	Closed	Wholesale Distributor	88-W-7195	3.14.25	Bowling Green, KY	State closed and issued new license number for the new location
OH	Surrendered	Wholesale Distributor	0130000429	6.23.25	Bowling Green, KY	State closed and issued new license number for the new location
UT	Surrendered	Wholesaler - Virtual	12649919-1710	3.2025	Bowling Green, KY	Relocated and not virtual anymore, applied for a new UT license

I, Rondal L. Turner, **certify that as the designated representative for** AZA Alliance Pharmaceuticals, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rondal L. Turner
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 10, 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ronda Turner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 10th, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Allen

I, Ronda Turner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

June 10, 2025

Date

Subscribed and Sworn to before me this 10th day of June 2025.

Notary Public Signature

MICHAEL ANTHONY MCGUIRE
NOTARY PUBLIC
Comm. # KYNP73383
COMMISSION EXPIRES 6/2/2027
COMMONWEALTH OF KENTUCKY

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site A2A Alliance Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 844-900-6001 Website https://www.a2aalliancepharma.us/

Licensing Company Email licenses@a2apharmgov.com

Section 2: Personal Information

First Rondal Middle Lee Last Turner

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Telephone 844-900-6001 Email licenses@a2apharmgov.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
United States Army War College		2009 - 2010	
Address	City	State	Zip
651 Wright Ave	Carlisle	PA	17013
Diploma/Degree obtained, if any			
Masters Degree of Strategic Studies			

School Name		From - To (MM/YY – MM/YY)	
Kentucky State University		1993 - 1994	
Address	City	State	Zip
400 E Main St	Frankfort	KY	40601
Diploma/Degree obtained, if any			
Masters Degree in Public Administration			

School Name		From - To (MM/YY – MM/YY)	
Western Kentucky University		1981- 1985	
Address	City	State	Zip
1906 College Heights Blvd	Bowling Green	KY	42101
Diploma/Degree obtained, if any			
Bachelors of Science in Agriculture			

School Name		From - To (MM/YY – MM/YY)	
Gamaliel High School		1978 - 1981	
Address	City	State	Zip
320 W Main Street	Gamaliel	KY	42140
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/13 - Present	[redacted]	Scottsville	KY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
A2A Alliance Pharmaceuticals, LLC		July 2020 - Present	
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite B	Franklin	KY	42134
Phone	**Title**		
844-900-6001	President + CEO		

Description of Duties

Turner manages the strategic infrastructure and foundation for A2A Alliance Pharmaceuticals to uphold the promise to deliver safe, effective and affordable FDA-approved pharmaceuticals and other medical related products to meet the customers' needs and ensure that patients and veterans have access to high-quality medicines when they need it.

Business Name		From - To (MM/YY – MM/YY)	
A2A Integrated Pharmaceuticals, LLC		Dec 2021 - Present	
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite A	Franklin	KY	42134
Phone	**Title**		
800-380-6709	Director of Govt. Strategies		

Description of Duties

Involved in the oversight of the activities e.g. private label repackaging and distribution of drug products.

Business Name		From - To (MM/YY – MM/YY)	
Allen County High School		08/11 - 12/20	
Business Address	**City**	**State**	**Zip**
570 W Oliver St.	Scottsville	KY	42164
Phone	**Title**		
270-6222-4119	Senior JROTC Instructor		

Description of Duties

Led and managed the high school JROTC program, overseeing instructional, operational, and administrative functions in accordance with U.S. Army Cadet Command regulations and school district policies.Supervised and mentored a team of JROTC instructors, ensuring effective delivery of the curriculum and fostering professional development.Developed and implemented comprehensive training schedules and lesson plans, integrating leadership education, citizenship, and physical fitness components.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	X	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
A2A Alliance Pharmaceuticals, LLC Licenses Voluntarily Surrendered				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached for list of surrendered licenses*

Original Signature (electronic, copies or stamps not accepted)

June 10 2025
Date

A2A Alliance Pharmaceuticals, LLC

75 Raines Drive, Suite B

Franklin, KY 42134

FEIN: 85-1797376

Surrendered/Closed License List

State	Status	License Type	License #	Date of Action	Location	Reason
AL	Surrendered	Wholesale - Virtual	196239	3.3.2025	Bowling Green, KY	Relocated and not virtual anymore, received a new AL license
WA	Surrendered	Wholesaler	PHWH.FX.61250716	3.13.25	Bowling Green, KY	State closed and issued new license number for the new location
OK	Closed	Wholesale Distributor	88-W-7195	3.14.25	Bowling Green, KY	State closed and issued new license number for the new location
OH	Surrendered	Wholesale Distributor	0130000429	6.23.25	Bowling Green, KY	State closed and issued new license number for the new location
UT	Surrendered	Wholesaler - Virtual	12649919-1710	3.2025	Bowling Green, KY	Relocated and not virtual anymore, applied for a new UT license

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rondal Turner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 10, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Allen

I, Rondal Turner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

June 10, 2025

Date

Subscribed and Sworn to before me this 10th day of June 25.

Notary Public Signature

MICHAEL ANTHONY MCGUIRE
NOTARY PUBLIC
Comm. # KYNP73383
COMMISSION EXPIRES 6/2/2027
COMMONWEALTH OF KENTUCKY

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site A2A Alliance Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 844-900-6001 Website https://www.a2aalliancepharma.us/

Licensing Company Email licenses@a2apharmgov.com

Section 2: Personal Information

First Ty Middle Jackson Last Downing

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Telephone 844-900-6001 Email licenses@a2apharmgov.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western Kentucky University		2011-2014	
Address	City	State	Zip
1906 College Heights Blvd	Bowling Green	KY	42101
Diploma/Degree obtained, if any			
Bachelors of science in Healthcare Administration			

School Name		From - To (MM/YY – MM/YY)	
Indiana University		2010-2011	
Address	City	State	Zip
107 S. Indiana Avenue	Bloomington	IN	47401
Diploma/Degree obtained, if any			
Informatics			

School Name		From - To (MM/YY – MM/YY)	
Greenwood High School		2006-2010	
Address	City	State	Zip
5065 Scottsville Rd.	Bowling Green	KY	42104
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/18 - Present	[redacted]	Bowling Green	KY	[redacted]
From - To (MM/YY – MM/YY)		City	State	
10/17 - 01/18		Pope	KY	
From - To (MM/YY – MM/YY)		City	State	
01/14 - 10/17		Bowling Green	KY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
A2A Alliance Pharmaceuticals			Jan 21 - Present
Business Address	**City**	**State**	**Zip**
75 Raines Dr. Suite B	Franklin	KY	42134
Phone	**Title**		
844-900-6001	VP of Distribution		

Description of Duties
Lead the strategic planning and execution of our pharmaceutical distribution operations, ensuring timely and compliant delivery of products across all channels. Optimize supply chain efficiency and uphold regulatory standards. My role focuses on enhancing operational performance, reducing costs, and maintaining the integrity of our products throughout the distribution process.

Business Name			From - To (MM/YY – MM/YY)
A2A Integrated Pharmaceuticals			01/20- Present
Business Address	**City**	**State**	**Zip**
75 Raines Dr. Suite A	Franklin	KY	42134
Phone	**Title**		
800-380-6709	Director Of Operations		

Description of Duties
Overseeing the daily operations of a company, ensuring that business processes are efficient and effective. Develops and implements operational strategies, managing budgets, and coordinating between departments to align operations with the company's goals.

Business Name			From - To (MM/YY – MM/YY)
DHP Healthcare			
Business Address	**City**	**State**	**Zip**
501 High St	Frankfort	KY	40601
Phone	**Title**		
270-512-2500	Owner & Partner		

Description of Duties
Collaborating on strategic planning, financial management, and operational decisions. Contributing expertise, overseeing specific business functions, and working closely with other partners to achieve the company's objectives.

Business Name			From - To (MM/YY – MM/YY)
R&S Pharmaceuticals			08/16- 01/18
Business Address	**City**	**State**	**Zip**
8407 Austin Tracy Rd.	Fountain Run	KY	42133
Phone	**Title**		
270-434-2045	Supply Chain Analyst		

Description of Duties
Monitoring inventory levels, forecasting demand, and identifying areas for cost reduction and process improvement. Collaborate with suppliers, manufacturers, and logistics partners to ensure timely delivery of products and materials, and develop strategies to optimize procurement, production, and distribution processes

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	X	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge A2A Alliance Pharmaceuticals, LLC Licenses Voluntarily Surrendered				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached for a full list of surrendered licenses*

Original Signature (electronic, copies or stamps not accepted)

6/10/2025

Date

A2A Alliance Pharmaceuticals, LLC

75 Raines Drive, Suite B

Franklin, KY 42134

FEIN: 85-1797376

Surrendered/Closed License List

State	Status	License Type	License #	Date of Action	Location	Reason
AL	Surrendered	Wholesale - Virtual	196239	3.3.2025	Bowling Green, KY	Relocated and not virtual anymore, received a new AL license
WA	Surrendered	Wholesaler	PHWH.FX.61250716	3.13.25	Bowling Green, KY	State closed and issued new license number for the new location
OK	Closed	Wholesale Distributor	88-W-7195	3.14.25	Bowling Green, KY	State closed and issued new license number for the new location
OH	Surrendered	Wholesale Distributor	0130000429	6.23.25	Bowling Green, KY	State closed and issued new license number for the new location
UT	Surrendered	Wholesaler - Virtual	12649919-1710	3.2025	Bowling Green, KY	Relocated and not virtual anymore, applied for a new UT license

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ty Downing

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/10/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Allen

I, Ty Downing, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

June 10, 2025

Date

Subscribed and Sworn to before me this 10th day of June 2025.

Notary Public Signature

MICHAEL ANTHONY MCGUIRE
NOTARY PUBLIC
Comm. # KYNP73383
COMMISSION EXPIRES 6/2/2027
COMMONWEALTH OF KENTUCKY

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site A2A Alliance Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 844-900-6001 Website https://www.a2aalliancepharma.us/

Licensing Company Email licenses@a2apharmgov.com

Section 2: Personal Information

First Douglas Middle Allen Last Taulbee

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Telephone 844-900-6001 Email licenses@a2apharmgov.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western Kentucky University		1981- 1985	
Address	**City**	**State**	**Zip**
1906 College Heights Blvd	Bowling Green	KY	42101
Diploma/Degree obtained, if any			
Bachelor of Science Accounting			

School Name		From - To (MM/YY – MM/YY)	
The Academies of Bryan Station		1978 - 1981	
Address	**City**	**State**	**Zip**
201 Eastin Rd	Lexington	KY	40505
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/21- Present	[redacted]	Alvaton	KY	
From - To (MM/YY – MM/YY)		City	State	Zip
06/95 - 06/21		Bowling Green	KY	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
A2A Integrated Pharmaceuticals, LLC			07/20 - Present
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite A	Franklin	KY	42134
Phone	**Title**		
800-380-6709	Chief Financial Officer		

Description of Duties
Oversee comprehensive financial reporting, including monthly and year-end statements, ensuring accuracy and compliance. Lead budgeting processes, implement robust financial controls, and manage investment activities to support organizational goals.

Business Name			From - To (MM/YY – MM/YY)
A2A Alliance Pharmaceuticals, LLC			07/20- Present
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite B	Franklin	KY	42134
Phone	**Title**		
800-380-6709	Chief Financial Officer		

Description of Duties
Oversee comprehensive financial reporting, including monthly and year-end statements, ensuring accuracy and compliance. Lead budgeting processes, implement robust financial controls, and manage investment activities to support organizational goals.

Business Name			From - To (MM/YY – MM/YY)
Rafferty's, Inc.			07/89 - 09/21
Business Address	**City**	**State**	**Zip**
1750 Scottsville Rd Suite 2	Bowling Green	KY	
Phone	**Title**		
270-780-3452	Chief Financial Officer		

Description of Duties
Drove financial strategy and operations, enhancing cash flow and building reserves exceeding $5 million through proactive debt management and cost control. Oversee comprehensive financial reporting, including monthly and year-end statements, ensuring accuracy and compliance. Lead budgeting processes, implement robust financial controls, and manage investment activities to support organizational goals.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	X	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1989		KY	Lexington	
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Douglas Taulbee received a DUI in Lexington KY in 1989. He received a fine and his license was suspended for 30 days. He has not had any other violations since then and it was not considered a felony.

Douglas A. Taulbee
Original Signature (electronic, copies or stamps not accepted)

6/5/25
Date

ARREST DATE	ORIGINAL CHARGE	LOCATION OF ARREST (city and state)	ARRESTING POLICE DEPARTMENT	DISPOSITION (e.g., guilty, not guilty, dismissed, etc.)
1989	DUI - Not a Felony	Lexington, KY	Lexington Police	Fine + License suspended for 30 days

9. Has a criminal indictment, information, or complaint ever been returned against you, but for which you were not arrested or which you were named as an un-indicted co-party? Yes ☐ No ☒ **If yes, give details on a separate page.**

10. Have you ever received a pardon or expungement for any criminal offense? Yes ☐ No ☒ **If yes, give details on a separate page. Include the charge, date, city, county and state.**

11. Have you ever been, or are you now, on parole/probation to any court? Yes ☐ No ☒ **If yes, give details on a separate page. Include the charges, the name of your parole/probation officer, location including city, county and state where probation was/is served.**

12. Have you ever been civilly or criminally subpoenaed to appear to testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒ **If yes, give details on a separate page. Include the location and reason for being subpoenaed.**

Complete the *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks. Follow instructions on the form for submitting fingerprints. The State Bureau of Identification will send the reports directly to the Board office.

AFFIDAVIT

I solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

Signature: Douglas A. Faulkner Date: 6/5/25

State of Kentucky Country of Allen

Subscribed and sworn to before me this 5th day of June, 2025

Witness my hand and seal hereunto attached.

Notary Signature: [signature]

SEAL My Commission expires: June 2, 2027

MICHAEL ANTHONY MCGUIRE NOTARY PUBLIC Comm. # KYNP73383 COMMISSION EXPIRES 6/2/2027 COMMONWEALTH OF KENTUCKY

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge
A2A Alliance has voluntarily surrendered licenses.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

*Please see attached for complete surrender list including explanations for each license.

Douglas A. Faulkee
Original Signature (electronic, copies or stamps not accepted)

6/5/25
Date

A2A Alliance Pharmaceuticals, LLC

75 Raines Drive, Suite B

Franklin, KY 42134

FEIN: 85-1797376

Surrendered/Closed License List

State	Status	License Type	License #	Date of Action	Location	Reason
AL	Surrendered	Wholesale - Virtual	196239	3.3.2025	Bowling Green, KY	Relocated and not virtual anymore, received a new AL license
WA	Surrendered	Wholesaler	PHWH.FX.61250716	3.13.25	Bowling Green, KY	State closed and issued new license number for the new location
OK	Closed	Wholesale Distributor	88-W-7195	3.14.25	Bowling Green, KY	State closed and issued new license number for the new location
OH	Surrendered	Wholesale Distributor	0130000429	6.23.25	Bowling Green, KY	State closed and issued new license number for the new location
UT	Surrendered	Wholesaler - Virtual	12649919-1710	3.2025	Bowling Green, KY	Relocated and not virtual anymore, applied for a new UT license

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Douglas Taulbee
Print Name (First, Last)

Douglas A. Taulbee
Original Signature (electronic, copies or stamps not accepted)

6/5/25
Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Allen

I, Douglas Taulbee, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Douglas A. Taulbee
Original Signature

6/5/25
Date

Subscribed and Sworn to before me this 5th day of June 2025

Notary Public Signature

MICHAEL ANTHONY MCGUIRE
NOTARY PUBLIC
Comm. # KYNP73383
COMMISSION EXPIRES 6/2/2027
COMMONWEALTH OF KENTUCKY

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site A2A Alliance Pharmaceuticals, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 844-900-6001 Website https://www.a2aalliancepharma.us/

Licensing Company Email licenses@a2apharmgov.com

Section 2: Personal Information

First Jack Middle Reed Last Downing

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 75 Raines Drive Suite B

City Franklin State KY Zip 42134

Telephone 844-900-6001 Email licenses@a2apharmgov.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Samford University School of Pharmacy		1990-1994	
Address	**City**	**State**	**Zip**
800 Lakeshore Drive	Birmingham	AL	35229
Diploma/Degree obtained, if any			
Bachelors of Science in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Monroe County High School		1982-1986	
Address	**City**	**State**	**Zip**
755 Old Mulkey Rd	Tomkinsville	KY	42167
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/18 - Present	[redacted]	Bowling Green	KY	[redacted]
06/17 - 05/18		Bowling Green	KY	
01/13 - 05/17		Bowling Green	KY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
A2A Alliance Pharmaceuticals			07/20 - Present
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite B	Franklin	KY	42134
Phone	**Title**		
844-900-6001	VP of Pharmaceutical Strategy		

Description of Duties
Assisted in managing corporate governance, growth strategies, and contract negotiations while supporting strategic partnerships to enhance market positioning, efficiency, and profitability. Contributed to supplier and client relationship management and provided industry expertise to support product and service development in the pharmaceutical sector.

Business Name			From - To (MM/YY – MM/YY)
A2A Integrated Pharmaceuticals			03/19- Present
Business Address	**City**	**State**	**Zip**
75 Raines Drive Suite A	Franklin	KY	42134
Phone	**Title**		
800-380-6709	President & CEO		

Description of Duties
Manages and develops the framework for corporate governance while establishing growth strategies and overseeing contract negotiations. Builds and maintains strategic partnerships and plays a key role in supplier and client relationship management to drive market positioning, efficiency, and profitability.

Business Name			From - To (MM/YY – MM/YY)
Downing Healthcare Partners			12/17- Present
Business Address	**City**	**State**	**Zip**
1680 Campbell Ln	Bowling Green	KY	42104
Phone	**Title**		
270-202-2461	Owner / Partner		

Description of Duties
Operates a My Eyelab franchise, part of a top 10 national optometry and optical chain. Appointed to the My Eyelab National Franchise Advisory Board in June 2019 and collaborates with the franchise operations team to support managed care and vendor partnerships

Business Name			From - To (MM/YY – MM/YY)
Sheldon's Express Retail Pharmacy			10/17 - Present
Business Address	**City**	**State**	**Zip**
843 Fairview Ave	Bowling Green	KY	42101
Phone	**Title**		
(270) 842-4515	Operational Pharmacy Supervisor		

Description of Duties
Oversees operations across five locations in three states, generating over $60 million in revenue and filling more than one million prescriptions annually. Collaborates with the CEO on quality control, growth strategies, new location launches, marketing, sales, and financial management. Leads employee training and strategic planning to enhance guest service, while maintaining strong communication with physicians, insurers, and patients to ensure accurate medication coordination and high client retention.

Business Name			From - To (MM/YY – MM/YY)
Downings Pharmacy Consulting			2008- Present
Business Address	**City**	**State**	**Zip**
4863 Scottsville Rd Ste C	Bowling Green	KY	42104
Phone	**Title**		
270-202-2461	President & Owner		

Description of Duties
Provides expert guidance to hospice organizations, specialty, compounding, and independent pharmacies by leveraging deep industry knowledge and operational insight. Acts as a subject matter expert on pharmacy operations, offering strategic solutions and tailored project approaches. Also consults with pharmaceutical manufacturers and distributors on business development, market growth, FDA pipeline analysis, and state licensure assessments

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
R&S Solutions			2011-2017
Business Address	**City**	**State**	**Zip**
96 American Dr	Jackson	TN	38301
Phone	**Title**		
270-590-1158	National Account Manager		

Description of Duties

Worked with pharmaceutical manufacturers, distributors, and government programs to facilitate the distribution of finished pharmaceutical products. Secured comprehensive service agreements by identifying company requirements and executing Certified Disclosure Agreements, Statements of Work, Quality Agreements, and full implementation proposals for brand product distribution through specialty programs.

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			2011-2017
Business Address	**City**	**State**	**Zip**
2824 Scottsville Rd	Bowling Green	KY	42104
Phone	**Title**		
270-393-2115	Pharmacy Manager		

Description of Duties

As a PCCA-accredited training member, prepared and processed prescriptions with a focus on accuracy and quality. Managed pharmacy operations and staff, fostering strong relationships with customers, healthcare providers, and drug reps, which improved efficiency and boosted profit margins. Also assisted in the negotiation and acquisition of independent pharmacies and served as an APhA Immunization Certified MTM provider, specializing in travel immunizations and the development of custom formulations, including topical Promethazine Gel.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	X	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
A2A Alliance has voluntarily surrendered licenses.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

*Please see attached for complete surrender list including explanations for each license.

Original Signature (electronic, copies or stamps not accepted)

June 10, 2025
Date

A2A Alliance Pharmaceuticals, LLC

75 Raines Drive, Suite B

Franklin, KY 42134

FEIN: 85-1797376

Surrendered/Closed License List

State	Status	License Type	License #	Date of Action	Location	Reason
AL	Surrendered	Wholesale - Virtual	196239	3.3.2025	Bowling Green, KY	Relocated and not virtual anymore, received a new AL license
WA	Surrendered	Wholesaler	PHWH.FX.61250716	3.13.25	Bowling Green, KY	State closed and issued new license number for the new location
OK	Closed	Wholesale Distributor	88-W-7195	3.14.25	Bowling Green, KY	State closed and issued new license number for the new location
OH	Surrendered	Wholesale Distributor	0130000429	6.23.25	Bowling Green, KY	State closed and issued new license number for the new location
UT	Surrendered	Wholesaler - Virtual	12649919-1710	3.2025	Bowling Green, KY	Relocated and not virtual anymore, applied for a new UT license

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JACK Downing
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 10, 2025
Date

Please have this section completed in the presence of a Notary Public.

State of Kentucky, ss. County of Allen

I, Jack Downing, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

June 10, 2025
Date

Subscribed and Sworn to before me this 10th day of June 2025

Notary Public Signature

MICHAEL ANTHONY MCGUIRE
NOTARY PUBLIC
Comm. # KYNP73383
COMMISSION EXPIRES 6/2/2027
COMMONWEALTH OF KENTUCKY

(Seal)

Last Name	First Name	Title	Company
Blankenship	Trena	Government Account Manager (Sales)	A2A Alliance Pharmaceuticals, LLC
Churchill	Winston	Director of Federal Government Sales	A2A Alliance Pharmaceuticals, LLC
Johnson	Carter	Supply Chain Manager	A2A Alliance Pharmaceuticals, LLC
Madison	Chris	Contracting Officer	A2A Alliance Pharmaceuticals, LLC
McGuire	Michael	Government Account Manager (Sales)	A2A Alliance Pharmaceuticals, LLC
Sims	Sheri	Director of Government Relations & Accounts	A2A Alliance Pharmaceuticals, LLC
Turner	Rondal	President & CEO A2A Alliance Pharmaceuticals	A2A Alliance Pharmaceuticals, LLC
Bartley	Josh	Director of Procurement & Sourcing Ops	A2A Integrated Pharmaceuticals, LLC
Cooper	Conner	Warehouse	A2A Integrated Pharmaceuticals, LLC
Doss	Lake	Graphic Designer	A2A Integrated Pharmaceuticals, LLC
Downing	Jack	President & CEO A2A Integrated Pharmaceuticals	A2A Integrated Pharmaceuticals, LLC
Downing	Ty	VP of Distribution Operations	A2A Integrated Pharmaceuticals, LLC
Eaton	John	Facilities Manager	A2A Integrated Pharmaceuticals, LLC
Grover	Gretchen	Director of Quality	A2A Integrated Pharmaceuticals, LLC
Jillela	Divya	Intern	A2A Integrated Pharmaceuticals, LLC
Kleis	Kim	Finance Controller	A2A Integrated Pharmaceuticals, LLC
Smith	Julianna	Chief Compliance Officer & Director of Regulatory	A2A Integrated Pharmaceuticals, LLC
Taulbee	Douglas	Chief Financial Officer	A2A Integrated Pharmaceuticals, LLC
Welch	Patrice	Director of Portfolio Management	A2A Integrated Pharmaceuticals, LLC
Witcher	Kacy	Regulatory Affairs Manager, Labeling	A2A Integrated Pharmaceuticals, LLC
Cieri	Bill	Director of Business Development/National Sales Advisor	Contract Employee
Lutz	Jaime	Accounting	Contract Employee
Napier	Kelly	Human Resources	Contract Employee

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: FedEx Supply Chain, Inc.

Physical Address: 5425 Exploration Dr., Suite 200

City: Indianapolis State: IN Zip: 46241

Mailing Address (if different from physical address): 145 Lt. George W. Lee Avenue

City: Memphis State: TN Zip: 38103

Telephone: 317-821-2748 Website: supplychain.fedex.com

Name of Designated Representative (DR): Timothy Woodard

Licensing Company Email: FSC-pharmalicensing@fedex.com DR Email: timothy.woodard@fedex.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Resilience US, LLC

Address: 10901 Kenwood Road City: Blue Ash State: OH Zip: 45242

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): FedEx Supply Chain Holdings, Inc.

Corporation/Organization Name: FedEx Supply Chain, Inc.

Mailing Address: 145 Lt. George W. Lee Avenue

City: Memphis State: TN Zip: 38103

Telephone: 901-455-0891 Email: fsc-pharmalicensing@fedex.com

Contact Person Name: Bria Scott

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

FedEx Supply Chain, Inc.
Facility Name

Bria Scott
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/25/2025
Date

Board Use Only	Date Received: 11/26/25	Amount: $1000.00

FedEx Supply Chain, Inc.

Incorporated in the State of Delaware on June 7, 1995

145 Lt. George W. Lee Ave, Memphis, TN 38103

FEIN: 25-1766580

FedEx Supply Chain Holdings, Inc.

Stockholder Ownership: 100%

Federal Tax ID: 88-0478924

Business Address: 145 Lt. George W. Lee Ave, Memphis, TN 38103

Business Phone: 901-455-0891

Email: FSC-pharmalicensing@fedex.com

Scott Temple, CEO/President

Federal Tax ID: 25-1766580

Business Address: 145 Lt. George W. Lee Ave, Memphis, TN 38103

Business Phone: 901-455-0891

Email: scott.temple@fedex.com

Courtney Keen, CFO/Vice President

Federal Tax ID: 25-1766580

Business Address: 145 Lt. George W. Lee Ave, Memphis, TN 38103

Business Phone: 901-455-0891

Email: courtney.keen@fedex.com

Secretary

Vacant

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "FEDEX SUPPLY CHAIN, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF MAY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203630772

Date: 05-07-25

2513710 8300

SR# 20252083386

You may verify this certificate online at corp.delaware.gov/authver.shtml

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000338A	09/30/2026

FedEx Supply Chain, Inc.
5425 Exploration Dr., Suite 200
Indianapolis IN 46241

Mike Braun
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Third Party Logistics Provider

Registration Number	Expire Date
94000338A	09/30/2026

FedEx Supply Chain, Inc.

Signature

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/17/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA, LLC. 6410 Poplar Avenue, Suite 540 Memphis, TN 38119 Attn: Memphis.Certs@marsh.com, P# 866-966-4684 CN103054409-FedEx-GAW-25-26	**CONTACT NAME:** **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:**
INSURED FedEx Supply Chain Distribution System, Inc. 50 Pennwood Place Warrendale, PA 15086	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Old Republic Insurance Co — 24147 **INSURER B :** ACE American Insurance Company — 22667 **INSURER C :** Indemnity Ins Co Of North America — 43575 **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** ATL-006096265-01 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			MWZY31577025	10/01/2025	10/01/2026	EACH OCCURRENCE	$	10,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	EXCLUDED
							PERSONAL & ADV INJURY	$	10,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	10,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	10,000,000
	OTHER:							$	
A	**AUTOMOBILE LIABILITY**			MWTB31576925	10/01/2025	10/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$	15,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
C	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY**			WLRC72797620 (AOS)	10/01/2025	10/01/2026	X PER STATUTE OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N **(Mandatory In NH)** N/A			SCFC72797632 (WI)	10/01/2025	10/01/2026	E.L. EACH ACCIDENT	$	5,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	5,000,000
							E.L. DISEASE - POLICY LIMIT	$	5,000,000
B	Excess Work Comp & Employers Liability			WCUC72797644 (Excess)(OH) (Self Insured Retention 450,000)	10/01/2025	10/01/2026	Statutory Comp		STATUTORY
							Employers Liability: Incls SIR		4,550,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: FedEx Supply Chain, Inc. – 12121 Forest Park Drive, Olive Branch, MS 38654
FedEx Supply Chain, Inc. – 5425 Exploration Drive, Indianapolis, IN 46241
FedEx Supply Chain, Inc. – 2901 Black Bridge Road, York, PA 17406
FedEx Supply Chain, Inc. – 5885 Sierra Avenue Ste. 200, Fontana, CA 92336
FedEx Supply Chain, Inc. – 3955 E Holmes Road. Memphis. TN 38118

CERTIFICATE HOLDER

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 016251682

Application/License No. _____

FedEx Supply Chain, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5425 Exploration Drive, Suite 200, Indianapolis, IN 46241 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 23, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23 day of October, 2025.

APPLICANT/PRINCIPAL
FedEx Supply Chain, Inc.

Authorized Representative

SURETY COMPANY
Liberty Mutual Insurance Company

Surety Company's Representative

Elizabeth A. Hartzberg, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

STEPHANIE C. ALLEN
Commission Number 852847
My Commission Expires
December 21, 2026

SIGNED and SEALED in the presence of:

Witness Dana McCaskey

Witness JoAnn R. Frank

Countersigned by:

N/A
Nevada Resident Agent
N/A

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Elizabeth A. Hartzberg

all of the city of Pittsburgh, state of Pennsylvania each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 23rd day of October, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: FedEx Supply Chain, Inc. MDEG License # (if applicable): N/A

Physical Address: 5425 Exploration Dr., Suite 200

City: Indianapolis State: IN Zip: 46241

Mailing Address (if different from physical address): 145 Lt. George W. Lee Ave.

City: Memphis State: TN Zip: 38103

Telephone: 317-821-2748 Website: supplychain.fedex.com

Licensing Company Email: FSC-pharmalicensing@fedex.com

Section 2: Personal Information

First: Timothy Middle: Leon Last: Woodard

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or IT[redacted] Sex ☐ M ☐ F ☐ X

Mailing Addres[redacted]

City: Brownsburg State: IN Zip: [redacted]

Telephon[redacted] Email: timothy.woodard@fedex.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ivy Tech Community College		08/06 - 06/10	
Address	**City**	**State**	**Zip**
50 W Fall Creek Pkwy N Dr	Indianapolis	IN	46208
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Ben Davis HS		08/02 - 06/05	
Address	**City**	**State**	**Zip**
1200 N Girls School road	Indianapolis	IN	46214
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/22 - Current	[redacted]	Brownsburg	IN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
9/17 - 10/22		Indianapolis	IN	
From - To (MM/YY – MM/YY)		City	State	
9/15 - 9/17		Indianapolis	IN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
FedEx Supply Chain, Inc.			10/24 - Current
Business Address	**City**	**State**	**Zip**
5425 Exploration Dr., Suite 200	Indianapolis	IN	46241
Phone	**Title**	**Number of Employed Hours**	
317-525-0623	Assistant General Manager	2,080	
Description of Duties			
Manages and oversees an operation that provides warehousing, document management and facilitates transportation and logisitcs of medical inventory.			

Business Name			From - To (MM/YY – MM/YY)
FedEx Suppy Chain, Inc.			
Business Address	**City**	**State**	**Zip**
1551 Perry Rd.	Plainfield	IN	46168
Phone	**Title**	**Number of Employed Hours**	
317-525-0623	Operations Manager	14,880	
Description of Duties			
Managed multiple operations that provided warehousing, document management and facilitated transporation and logistics of medical inventory.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1/24/2005	2/10/2025	IN	Indianapolis	Marion
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
49D23250 2XP005925		Marion County Superior Court		
Reason/Charge				
Resisting Law Enforcement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Recieved expungement for resisting arrest charge that occurred twenty years ago while in highschool. Expungement document attached.

Per Month, fp were clear - Disclosure was expunged. No Dave/reph review

Original Signature (electronic, copies or stamps not accepted)

11/15/2025
Date

I, Timothy Woodard, **certify that as the MDEG Administrator for**

FedEx Supply Chain, Inc.,

that I (initial that you have read and meet the following requirements):

1. X Have a high school diploma or its equivalent;
2. X Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. X Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. X Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Timothy Woodard
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11 15 2025
Date

Board Use Only	Date Received:

FILED
February 11, 2025
CLERK OF THE COURT
MARION COUNTY
RM

NOT PUBLIC RECORD

STATE OF INDIANA	)	**IN THE MARION SUPERIOR COURT**
	)SS:	**CIVIL DIVISION , ROOM**
COUNTY OF MARION	)	**CAUSE NO.: 49D02-2502-XP-005925**
		☐ An exhibit listing additional case numbers is attached
IN RE THE PETITION FOR	)	**Related Criminal Cause Numbers:**
EXPUNGEMENT OF CONVICTION	)	49F19-0501-CM-010594
RECORDS OF:	)	
TIMOTHY LEON WOODARD ,	)	
Petitioner.	)	

FINDINGS AND ORDER GRANTING PETITIONER'S VERIFIED PETITION FOR EXPUNGEMENT OF CONVICTION RECORDS PURSUANT TO I.C. 35-38-9

Petitioner, Timothy Leon Woodard, [by counsel, _____,] filed this *VERIFIED PETITION FOR EXPUNGEMENT OF CONVICTION RECORDS PURSUANT TO I.C. 35-38-9*, and the State of Indiana, by counsel, ☐ filed ☐ did not file its Response to Petitioner's Verified Petition for Expungement.

Petitioner's Verified Petition for Expungement seeks relief as provided by I.C. 35-38-9 for multiple cases arising out of Marion County, Indiana that resulted in convictions.

☐ Upon review of said Petition ☐ and the State of Indiana's Response, the Court finds that the State has provided no legal basis upon which to state an objection to the Court's granting of Petitioner's Verified Petition for Expungement/Sealing of Arrest Records.

☐ A hearing was held on _____ regarding said Petition of which all parties were given notice and during which all parties were given an opportunity to present evidence and arguments.

FINDINGS AS TO ALL EXPUNGEMENT MATTERS:

The Court now finds by a preponderance of the evidence that:

1. Petitioner's Verified Petition for Expungement complies with the requirements of I.C. 35-38-9-8.
2. Consistent with the provisions of I.C. 35-38-9-9(i) and except as provided in I.C. 35-38-9-9(j) and (k), Petitioner has only filed one (1) Verified Petition for Expungement in [her] lifetime.
3. The following is a list of petitions to address convictions that are eligible for expungement under I.C. § 35-38-9-2 through 5 that the petitioner has filed or will be filing in other Indiana counties:

N/A

☐ An additional page has been attached to the end of this petition, marked as "Exhibit," listing additional expungement petitions filed in other Indiana counties.

4. No charges are currently pending against Petitioner.

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FINDINGS AS TO EXPUNGEMENT MATTER 1 :

☑ **CONVICTION FOR A MISDEMEANOR**

☐ **CONVICTION FOR A FELONY THAT WAS REDUCED TO A MISDEMEANOR**

The Court now finds by a preponderance of the evidence that:

1. Petitioner's verified petition for expungement seeks relief as provided by I.C. 35-38-9-2 for a conviction entered on the following charges on 7/13/2005, under Cause Number 49F19-0501-CM-010594 in Marion Superior, Criminal Division, Room 19

   a. RLE class A misdemeanor;
   b. _____;
   c. _____;
   d. _____;

   ☐ said felony judgment was converted to a Class A Misdemeanor on _____.

2. Petitoner is not a person who is prohibited from seeking this remedy under the provisions of I.C. §35-38-9-2(b).

3. Elapsed time:

   ☑ Five (5) years have elapsed between the date of Petitioner's conviction and the filing of this Petition.

   ☐ The Marion County Prosecuting Attorney has provided written consent for a shorter elapsed time period.

4. Criminal activity within the previous 5 years:

   ☑ Petitioner has not been convicted of another crime in any jurisdiction within the previous five (5) years.

   ☐ Petitioner has not been convicted of another crime in any jurisdiction within the shorter elapsed time period to which the prosecuting attorney has agreed.

5. Petitioner has:

   ☑ Paid all fines, fees, and court costs, and no restitution obligation was imposed as part of his sentence.

   ☐ Satisfied his restitution obligation of $_____ imposed as part of his sentence.

   ☐ Been found indigent as to all outstanding fines, costs, and fees ordered as part of his sentence.

6. Appellate activity:

   ☑ The case that Petitioner is requesting be sealed has not been appealed.

   ☐ The case that Petitioner is requesting be sealed was appealed on _____ under the following appellate cause number: _____

7. Related MC cause numbers:

   ☐ Court records stored under the following MC case/cause numbers constitute records of the sentencing court or juvenile court for the purposes of this order:

   n/a

The Court now finds that the Petition as to EXPUNGEMENT MATTER 1 shall be GRANTED.

NOT PUBLIC RECORD

ORDER

It is therefore ORDERED, ADJUDGED, and DECREED that Petitioner's Verified Petition for Expungement is GRANTED as to EXPUNGEMENT MATTERS: _____ and DENIED as to EXPUNGEMENT MATTERS: _____. All information necessary to identify particular agency records that are to be expunged pursuant to this Order has been included in **Exhibit A** attached to this Order.

1. **As to all EXPUNGEMENT MATTERS for which an expungement is granted:** The following provisions of this Order shall apply to all except those persons or entities specifically listed to whom sealed records may be disclosed pursuant to paragraph 2(b) of this Order:
   a. Except as provided in I.C. § 35-38-9-6(f), Petitioner's civil rights shall be restored, including the right to vote, to hold public office, to be a proper person under IC 35-47-1-7(2), and to serve as a juror.
   b. It is unlawful discrimination for any person to:
      i. suspend;
      ii. expel;
      iii. refuse to employ;
      iv. refuse to admit;
      v. refuse to grant or renew a license, permit, or certificate necessary to engage in any activity, occupation, or profession; or
      vi. otherwise discriminate against;

      Petitioner because of a conviction or arrest record expunged or sealed under this Order.
   c. In any application for employment, a license, or other right or privilege, Petitioner may be questioned about a previous criminal record only in terms that exclude expunged convictions or arrests.
   d. Petitioner shall be treated as if Petitioner had never been convicted of the offense. However, upon subsequent arrest or conviction for an unrelated offense, the expunged conviction: (1) may be considered by the Court in determining the sentence imposed for the new offense; (2) is a prior unrelated conviction for the purposes of a habitual offender enhancement and enhancing the new offense based on a prior conviction; and (3) may be admitted as evidence in the proceeding for a new offense as if the conviction had not been expunged.
   e. If Petitioner is required to register as a sex offender based on the commission of a felony that has been expunged in accordance with this Order:
      i. the expungement does not affect the operation of the sex offender registry web site, any person's ability to access Petitioner's records, records required to be maintained concerning sex or violent offenders, or any registration requirement imposed on the Petitioner; and
      ii. the expunged conviction must be clearly marked as expunged on the sex offender registry web site.

f. Expungement of any conviction records in accordance with this order does not affect any existing or pending driver's license suspension.

g. Nothing in this Order should be construed to prevent the Indiana Bureau of Motor Vehicles from reporting information about conviction for a violation of a traffic control law to the Commercial Drivers License Information System (CDLIS) in accordance with I.C. § 9-24-6-2(d).

2. **As to EXPUNGEMENT MATTERS** _____ of Petitioner's records, including but not limited to conviction records and records of all dismissed charges, not file charges, and not guilty charges, under the following Cause Numbers, are expunged in accordance with Indiana Code 35-38-9-6:

49F19-0501-CM-010594

a. **Records in possession of state and local agencies and service providers:** The following agencies and entities are hereby prohibited from releasing Petitioner's records or information in Petitioner's records to anyone without a court order, other than a law enforcement officer acting in the course of the officer's official duty:

i. The Indiana Department of Corrections;

ii. The Indiana Bureau of Motor Vehicles, except as provided in paragraph 1(g) of this Order;

iii. Each law enforcement agency who incarcerated, provided treatment for, or provided other services for the person under an order of the court, including:

(a) IMPD ;

(b) _____; and

iv. Each person or entity who incarcerated, provided treatment for, or provided other services for the person under an order of the court, including:

(a) n/a ;

(b) n/a .

b. **Records in possession of the Indiana State Police Central Records Repository:** In accordance with I.C. 35-38-9-6(a)(2), the Indiana State Police Central Repository for Criminal History Information is ordered to seal all of Petitioner's records for Cause Number _____. This includes, but is not limited to, convictions in this cause, counts that were not filed or dismissed in this cause, counts where there was a finding of not guilty in this cause any reference to an arrest in this cause, and any reference to any other matters in this case. The Central Repository is also prohibited from disclosing these records to anyone except:

i. a prosecuting attorney, if:
(a) authorized by a court order; and
(b) needed to carry out the official duties of the prosecuting attorney;

ii. a defense attorney, if:
(a) authorized by a court order; and
(b) needed to carry out the professional duties of the defense attorney

iii. a probation department, if:
(a) authorized by a court order; and
(b) necessary to prepare a presentence report; and

iv. the Federal Bureau of Investigation and the Department of Homeland Security, if disclosure is required to comply with an agreement relating to the sharing of criminal history information;

v. the:
(a) supreme court;
(b) members of the state board of law examiners;
(c) executive director of the state board of law examiners; and
(d) employees of the state board of law examiners, in accordance with rules adopted by the state board of law examiners;

for the purpose of determining whether an applicant possesses the necessary good moral character for admission to the bar;

vi. a person required to access expunged records to comply with the Secure and Fair Enforcement for Mortgage Licensing Act (12 U.S.C. 5101 et seq.) or regulations adopted under the Secure and Fair Enforcement for Mortgage Licensing Act; and

vii. the bureau of motor vehicles, the Federal Motor Carrier Administration, and the Commercial Drivers License Information System (CDLIS), if disclosure is required to comply with IC 9-24-6-2(d) relating to reporting a conviction for a violation of a traffic control law.

c. **Records of the sentencing court, the juvenile court, the Court of Appeals and the Supreme Court:** Except as provided in I.C. 35-38-9-6(d), the records of the sentencing court, a juvenile court, the Court of Appeals of Indiana, and the Indiana Supreme Court concerning Petitioner shall be permanently sealed.

d. As to court records stored under the following appellate/post conviction relief cause numbers:

_____

_____,

the Clerk shall send a copy of this Order to the Clerk of the Indiana Supreme Court, and Clerk of the Supreme Court shall:

i. redact any opinion or memorandum decision in which the Petitioner has been named as it appears on the computer gateway administered by the office of technology so that it does not include the petitioner's name (in the same manner by which opinions involving juveniles are redacted); and

ii. provide a redacted copy of the opinion to any publisher or organization to whom the opinion or memorandum decision is provided after the date of the order of expungement.

e. The Clerk shall send a copy of this Order to all parties of record or their attorneys to the Indiana State Police Central Repository for Criminal History, to the Indiana Department of Corrections, to the Indiana Bureau of Motor Vehicles, and the following law enforcement agencies or entities that possess records related to Petitioner's conviction:

i. The Marion County Sheriff's Department

ii. The local law enforcement agencies:

(a) IMPD;

(b) _____;

iii. All persons or entities who incarcerated, provided treatment for, or provided other services for the person under an order of the court, including:

(a) n/a ;

(b) n/a .

3. **As to EXPUNGEMENT MATTERS** _____

(pertaining to records related to the following criminal and MC cause numbers:

N/A

),

Petitioner's conviction records shall be **expunged in accordance with I.C. 35-38-9-7,** specifically:

a. All court records and other public records relating to the arrest, conviction, or sentence of Petitioner that have been marked expunged shall remain public records. However, the Court now orders that those records be clearly and visibly marked or identified as being expunged.

b. The following agencies and entities in possession of records that relate to the conviction ordered to be marked as expunged shall add an entry to Petitioner's record of arrest, conviction, or sentence in the criminal history database stating that the records are marked as expunged:

i. The Indiana Department of Correction;

ii. The Indiana Bureau of Motor Vehicles;

iii. Each law enforcement agency who incarcerated, provided treatment for, or provided other services for the person under an order of the court:

(a) IMPD ;

(b) _____ ; and

iv. Each person or entity who incarcerated, provided treatment for, or provided other services for the person under an order of the court, including

(a) n/a ;

(b) n/a .

c. The Clerk shall send a copy of this Order to all parties of record or their attorneys, to the Indiana State Police Central Repository for Criminal History; to the Indiana Department of Correction, to the Indiana Bureau of Motor Vehicles, and the following law enforcement agencies or entities that possess records related to Petitioner's conviction:

i. The Marion County Sheriff's Department

ii. The local law enforcement agencies:

(a) IMPD

(b) _____

iii. All persons or entities who incarcerated, provided treatment for, or provided other services for the person under an order of the court, including:

(a) n/a

(b) n/a

d. As to court records stored under the following appellate/post conviction relief cause numbers:

the Clerk shall send a copy of this Order to the Clerk of the Indiana Supreme Court, and:

i. all court records and other public records relating to the arrest, conviction, or sentence shall remain public records;

ii. the records shall be clearly and visibly marked or identified as being expunged.

SO ORDERED this 2/10/2025.

GRANTED
February 10, 2025

JUDGE | MAGISTRATE | COMMISSIONER
MARION SUPERIOR Court,
CIVIL DIVISION , Room

Notice to be given by: ____ Court ____ Clerk ____ Other:

PROOF OF NOTICE

A copy of the entry was served either by mail to the address of record, deposited in the attorney's distribution box, or personally distributed to the following persons:

State of Indiana:
Petitioner:

Date of notice:
Initial of person who notified parties: _____ Court _____ Clerk _____ Other

Distribution To:

☐ _____
Attorney for Petitioner

☐ Timothy Leon Woodard
Petitioner
[redacted]

Marion County Prosecutor's Office
Attn:
251 E. Ohio Street, Suite 160
Indianapolis, IN 46204

Marion County Sheriff's Department
675 Justice Way
Indianapolis, IN 46203

Indiana State Police
Attn: Records Division
100 N Senate Ave., Room N301 (East)
Indianapolis, IN 46204

Bureau of Motor Vehicles
IGC North, Room 402
100 North Senate Avenue
Indianapolis, IN 46204

Indiana Department of Correction
Attn: Records Division
302 W. Washington Street, Room E-334
Indianapolis, IN 46204

Office of the Indiana Attorney General
Indiana Government Center South, 5th Floor
302 W. Washington Street
Indianapolis, IN 46204

☐ _____ County Clerk

_____

_____

[check this box only if this ORDER applies to court records stored under a separate MC cause number that pertain to a PROBATION that was transferred to another county.]

Law Enforcement Agencies:

Indianapolis Metropolitan Police Dept.
50 N. Alabama St.
Indianapolis, IN 46204

☐ Clerk of the Appellate Courts
216 State House
200 West Washington Street
Indianapolis, IN 46204
[check this address only if one or more of the expunged cases was appealed.]

☐ Indiana Supreme Court
Office of Court Services
Court Technology
251 N. Illinois St., Suite 700
Indianapolis, IN 46204
[check this address only if a NO CONTACT ORDER was issued in one or more of the expunged cases as a condition of BOND or PROBATION.]

Other persons or entities that required to act under this order because they possess official records related to the expunged convictions:

_____
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EXHIBIT A, Page __ of ____:

FINDINGS AND ORDER GRANTING PETITION FOR EXPUNGEMENT OF CONVICTION RECORDS PURSUANT TO I.C. 35-38-9 (XP Cause Number:)

EXPUNGEMENT MATTER I ,

PETITIONER IDENTIFICATION INFORMATION:

Full Name: Timothy Leon Woodard

[redacted]

Alias Names, DOBs and SSNs:
N/A

Addresses since first criminal offense addressed in this Order:
In Indianapolis [redacted]
In Louisville KY

INDIVIDUAL ARREST INFORMATION:

Criminal Cause Number: 49F19-0501-CM-010594
n/a

Arresting Agency: unknown
County/City of Arrest: Marion/Indpls.
Law Enforcement Agency Case Number: unknown

Date of Arrest: 01/24/2005 Date of Conviction: 7/13/2005

List of Charges:	Disposition of Charges:
RLE, class A misdemeanor	Guilty

☐ Expunged pursuant to I.C. § 35-38-9-6

☐ Expunged pursuant to I.C. § 35-38-9-7

☐ NOT expunged

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: FedEx Supply Chain, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 5425 Exploration Dr., Suite 200

City: Indianapolis State: IN Zip: 46241

Mailing Address (if different from physical address): 145 Lt. George W. Lee Ave.

City: Memphis State: TN Zip: 38103

Telephone: 317-821-2748 Website: supplychain.fedex.com

Licensing Company Email: FSC-pharmalicensing@fedex.com

Section 2: Personal Information

First: Timothy Middle: Leon Last: Woodard

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Brownsburg State: IN Zip: [redacted]

Telephone: [redacted] Email: timothy.woodard@fedex.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ivy Tech Community College		08/06 - 06/10	
Address	**City**	**State**	**Zip**
50 W Fall Creek Pkwy N Dr	Indianapolis	In	46208
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Ben Davis HS		08/02 - 06/05	
Address	**City**	**State**	**Zip**
1200 N Girls School road	Indianapolis	IN	46214
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/22 - Current	[redacted]	Brownsburg	IN	[redacted]
9/17 - 10/22		Indianapolis	IN	
9/15 - 9/17		Indianapolis	IN	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
FedEx Supply Chain			10/24 - Current	
Business Address		City	State	Zip
5425 Exploration dr		Indianapolis	IN	46241
Phone	Title		Number of Employed Hours	
317-525-0623	Assistant General Manager		2,080	
Description of Duties				
Manages and oversees an operation that provides warehousing, document management and facilitates transportation and logistics of medical inventory.				

Business Name			From - To (MM/YY – MM/YY)	
Fedex Supply Chain			07/17 - 10/24	
Business Address		City	State	Zip
1551 Perry rd		Plainfield	IN	46168
Phone	Title		Number of Employed Hours	
317-525-0623	Operations Manager		14,880	
Description of Duties				
Managed multiple operations that provided warehousing, document management and facilitated transportation and logistics of medical inventory.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Timothy Leon Woodard, **certify that as the designated representative for**

FedEx Supply Chain, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TW I am at least 21 years of age;
3. TW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Timothy Leon Woodard
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/17/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Timothy Leon Woodard

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/17/25

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hendricks

I, Timothy Woodard, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/17/25

Date

Subscribed and Sworn to before me this 17 day of October 2025

Notary Public Signature

KALEENA KELSO
Notary Public - Seal
Marion County - State of Indiana
Commission Number NP0740420
My Commission Expires Apr 10, 2030

(Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/24/2005	2/10/2025	Indiana	Indianapolis	Marion
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
49D232502XP005925		Marion County Superior Court		
Reason/Charge				
Expungement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

The expungement was filed for a resisting arrest charge I received during high school twenty years ago. Documentation attached.

Original Signature (electronic, copies or stamps not accepted)

10/17/2025
Date



FedEx Supply Chain, Inc.
5425 Exploration Dr., Suite 200
Indianapolis, IN 46241

To the Nevada Board of Pharmacy,

Please see the employee list for the Indiana Logistics Center facility for FedEx Supply Chain, Inc:

Assistant General Manager – Timothy Woodard
Operations Supervisor – Rodney Nelson
Quality Specialist – Jeffrey Thomas
S/R Clerk – Kimberly Moore
Inventory Clerk – Taijah Nelson
LTO – Fredderick Brent
LTO – Roger Watson
LTO – McKinley Gibbs

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Schraders Medical Supply, Inc.

Physical Address: 5507 Brooks Street

City: Montclair State: CA Zip: 91763

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 9094477040 Website: www.schradersms.com

Name of Designated Representative (DR): Kristina McIntosh

Licensing Company Email: kmcintosh@schradersms.com DR Email: kmcintosh@schradersms.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Abbott
Address: 75 Remittance Drive City: Chicago State: IL Zip: 60675

Name: Nestle Nutrition
Address: PO Box 3637 City: Boston State: MA Zip: 02241

Name: Amsino International
Address: 708 Corporate Drive City: Pomona State: CA Zip: 91768

Name: Cardinal Health
Address: PO Box 100316 City: Pasadena State: CA Zip: 91189

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: Kristina McIntosh
Business Name: Schraders Medical Supply, Inc.
Business Address: 5507 Brooks Street
City: Montclair State: CA Zip: 91763
Telephone: 9095423209 Email: kmcintosh@schradersms.com

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Abbott
Address: 75 Remittance Drive City: Chicago State: IL Zip: 60675

Name: Nestle Nutrition
Address: PO Box 3637 City: Boston State: MA Zip: 02241

Name: Amsino International
Address: 708 Corporate Drive City: Pomona State: CA Zip: 91768

Name: Cardinal Health
Address: PO Box 100316 City: Pasadena State: CA Zip: 91189

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CA
Parent Company (if any):
Corporation/Organization Name: Schraders Medical Supply, Inc.
Mailing Address: 5507 Brooks Street
City: Montclair State: CA Zip: 91763
Telephone: 9094477040 Email: kmcintosh@schradersms.com
Contact Person Name: Kristina McIntosh

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: Kristina McIntosh
Business Name: Schraders Medical Supply, Inc.
Business Address: 5507 Brooks Street
City: Montclair State: CA Zip: 91763
Telephone: 9095423209 Email: kmcintosh@schradersms.com

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NONE. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:
NONE

Original Signature (electronic, copies or stamps not accepted)

10/9/2025
Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Schraders Medical Supply, Inc

Facility Name

Kristina McIntosh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/9/2025

Date

Board Use Only	Date Received: 10/27/25	Amount: $1000-CK 027486

Schraders
Medical Supply, Inc.

November 18, 2025

List of owners, officers, members:

Owner - Kristina McIntosh, 100% owner

Officer – Kristina McIntosh, President, CEO, CFO, Secretary and Treasurer

5507 Brooks Street | Montclair | CA 91763 | 800-258-9145 | Fax 909-447-7030

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	SCHRADERS' MEDICAL SUPPLY, INC.
Entity No.:	1723107
Registration Date:	04/07/1993
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of December 02, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 393750732

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.



Renewal License

Wholesale Drug Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

License No. WLS 4153
Receipt No. 52160381

Valid Until: 10/1/2026

SCHRADERS MEDICAL SUPPLY INC
5507 BROOKS STREET
MONTCLAIR, CA 91763

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Schraders Medical Supply Inc
5507 Brooks Street
Montclair, CA 91763

LICENSE NUMBER: 126859
EXPIRATION DATE: 10/16/2026

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 10/17/2025

DOMESTIC CHEMICAL DIVERSION CONTROL REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
004896SIY	02-28-2026	$1850

BUSINESS ACTIVITY	ISSUE DATE
CHEMICAL DISTRIBUTOR	01-06-2025

SCHRADERS' MEDICAL SUPPLY INC
SCHRADERS MEDICAL SUPPLY INC.
5507 BROOKS STREET
MONTCLAIR, CA 917634547

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, import or export a List 1 chemical.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-511 (9/2016)

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/05/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER

State Farm

Cline Insurance Agency, Inc.
DBA: Kyle Cline Insurance Agency, Inc.
1275 E. Route 66
Glendora, CA 91740

CONTACT NAME: Kyle Cline
PHONE (A/C, No, Ext): 626-335-0815 FAX (A/C, No): 626-335-0850
E-MAIL ADDRESS: Kyle.cline.jftk@statefarm.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : State Farm General Insurance Company	25151
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED

Schraders Medical Supply Inc.
5507 Brooks St
Montclair, CA 91763

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADD INSD	SUB WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [ ] LOC OTHER:			92-BX-Y627-5	05/01/2025	05/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 300,000 $ 10,000 $ $ 2,000,000 $ 2,000,000
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
A	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION $			92-W3-9828-7	05/01/2025	05/01/2026	EACH OCCURRENCE AGGREGATE	$ 6,000,000 $ 6,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Kyle Cline

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 5342419

Application/License No. MP00951

Schraders' Medical Supply, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5507 Brooks St, Montclair, CA 91763-4547 (Address of Applicant/Principal), as PRINCIPAL, and SureTec Insurance Company (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2103 CityWest Blvd., Ste. 1300, Houston, TX 77042-2832 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of One Hundred Thousand Dollars and Zero Cents DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 13, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions: Bond No. 5342419

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of October, 2025.

APPLICANT/PRINCIPAL
Schraders' Medical Supply, Inc.

Authorized Representative

SURETY COMPANY
SureTec Insurance Company

Surety Company's Representative

Michael K. Herman, Jr., Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

POA #: 5342419

SureTec Insurance Company
LIMITED POWER OF ATTORNEY

Know All Men by These Presents, That SURETEC INSURANCE COMPANY (the "Company"), a corporation duly organized and existing under the laws of the State of Texas, and having its principal office in Houston, Harris County, Texas, does by these presents make, constitute and appoint

Michael K. Herman, Jr.

its true and lawful Attorney-in-fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings or other instruments or contracts of suretyship to include waivers to the conditions of contracts and consents of surety for:

Schraders' Medical Supply, Inc. (Principal)
Nevada State Board of Pharmacy (Obligee)
$100,000.00 (Penalty Amount)

and to bind the Company thereby as fully and to the same extent as if such bond were signed by the President, sealed with the corporate seal of the Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolutions of the Board of Directors of the SureTec Insurance Company:

Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and of behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached. *(Adopted at a meeting held on 20th of April, 1999.)*

In Witness Whereof, SURETEC INSURANCE COMPANY has caused these presents to be signed by its President, and its corporate seal to be hereto affixed this 3rd day of February, A.D. 2023.

SURETEC INSURANCE COMPANY

By: _____
Michael C. Keimig, President

State of Texas ss:
County of Harris

On this 3rd day of February, A.D. 2023 before me personally came Michael C. Keimig, to me known, who, being by me duly sworn, did depose and say, that he resides in Houston, Texas, that he is President of SURETEC INSURANCE COMPANY, the company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said Company; and that he signed his name thereto by like order.

TANYA SNEED
Notary Public State of Texas
Commission # 128571231
Commission Expires 03/30/2027

_____
Tanya Sneed, Notary Public
My commission expires March 30, 2027

I, M. Brent Beaty, Assistant Secretary of SURETEC INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Company, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

Given under my hand and the seal of said Company at Houston, Texas this 13th day of October, 2025, A.D.

_____
M. Brent Beaty, Assistant Secretary

Any instrument issued in excess of the penalty stated above is totally void and without any validity.
For verification of the authority of this power, contact bondverification@markel.com

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles)

On Oct. 13, 2025 before me, Michelle M. Herman, Notary Public
(insert name and title of the officer)

personally appeared Michael K. Herman, Jr.,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

MICHELLE M. HERMAN
Notary Public · California
Los Angeles County
Commission # 2514462
My Comm. Expires Mar 15, 2029

Signature Michelle M. Herman (Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Schraders Medical Supply, Inc. MDEG License # (if applicable): MP00951

Physical Address: 5507 Brooks Street

City: Montclair State: CA Zip: 91763

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 9094477040 Website: www.schradersms.com

Licensing Company Email: kmcintosh@schradersms.com

Section 2: Personal Information

First: Kristina Middle: M Last: McIntosh

Alias(es, nicknames, name changes, etc.): Schrader

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Upland State: CA Zip: [redacted]

Telephone: [redacted] Email: kmcintosh@schradersms.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
California Lutheran University			01/1998-02/2000	
Address		City	State	Zip
60 W. Olsen Road		Thousand Oaks	CA	91360
Diploma/Degree obtained, if any				
Master of Business Administration				
School Name			From - To (MM/YY – MM/YY)	
Cal Poly Pomona			06/1990-06/1992	
Address		City	State	Zip
3801 W. Temple Avenue		Pomona	CA	91768
Diploma/Degree obtained, if any				
Bachelor of Science				
School Name			From - To (MM/YY – MM/YY)	
Citrus College			06/1987-06/1989	
Address		City	State	Zip
1000 W. Foothill Blve		Glendora	CA	91741
Diploma/Degree obtained, if any				
Associates of Science				
School Name			From - To (MM/YY – MM/YY)	
Danbury High School			1984-1987	
Address		City	State	Zip
3 Clapoard Road		Danbury	CT	06811
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012-Current	[redacted]	Upland	CA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2018 - 2020		Claremont	CA	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Schraders Mediacal Supply, Inc.		09/2008 - Current	
Business Address	**City**	**State**	**Zip**
5507 Brooks Street	Montclair	CA	91763
Phone	**Title**	**Number of Employed Hours**	
909-367-6494	President	35,360	
Description of Duties			
Manage all operations			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NONE. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

NONE

Original Signature (electronic, copies or stamps not accepted)

10/9/2025
Date

I, Kristina McIntosh, **certify that as the MDEG Administrator for**

Schraders Medical Supply, Inc.,

that I (initial that you have read and meet the following requirements):

1. KM Have a high school diploma or its equivalent;
2. KM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristina McIntosh

Print Name (First, Last)

K. McIntosh

Original Signature (electronic, copies or stamps not accepted)

10/9/25

Date

Board Use Only	Date Received: 10/27/25

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Schraders Medical Supply, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5507 Brooks Street

City Montclair State CA Zip 91763

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 909-447-7040 Website www.schradersms.com

Licensing Company Email kmcintosh@schradersms.com

Section 2: Personal Information

First Kristina Middle Marie Last McIntosh

Alias(es, nicknames, name changes, etc.) Schrader

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Upland State CA Zip [redacted]

Telephone [redacted] Email kmcintosh@schradersms.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X

2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name CALIFORNIA LUTHERAN UNIVERSITY		From - To (MM/YY – MM/YY) 01/1998-02/2000	
Address 60 W. OLSEN ROAD	City THOUSAND OAKS	State CA	Zip 91360
Diploma/Degree obtained, if any MASTERS OF BUSINESS ADMINISTRATION			
School Name CAL POLY POMONA		From - To (MM/YY – MM/YY) 06/1990-06/1992	
Address 3801 W. TEMPLE AVENUE	City POMONA	State CA	Zip 91768
Diploma/Degree obtained, if any BACHELORS OF SCIENCE			
School Name CITRUS COLLEGE		From - To (MM/YY – MM/YY) 06/1987 – 06/1989	
Address 1000 W. FOOTHILL BLVD	City GLENDORA	State CA	Zip 91741
Diploma/Degree obtained, if any			
School Name DANBURY HIGH SCHOOL		From - To (MM/YY – MM/YY) 1984-1987	
Address 3 CLAPBOARD RIDGE RD	City DANBURY	State CT	Zip 06811
Diploma/Degree obtained, if any HIGH SCHOOL DIPLOMA			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY) 2012-CURRENT	Address [redacted]	City UPLAND	State CA	Zip [redacted]
From - To (MM/YY – MM/YY) 2018-2020		City CLAREMONT	State CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name SCHRADERS MEDICAL SUPPLY, INC.			From - To (MM/YY – MM/YY) 09/2008-CURRENT
Business Address 5507 BROOKS STREET	City MONTCLAIR	State CA	Zip 91763
Phone 909-447-7040	Title PRESIDENT		Number of Employed Hours 40,000+
Description of Duties Manage all operations of the company for the past 17 years. I have a complete understanding of the products we carry and sell, especially those that are under Rx and wholesaler Requirements. I ensure our record keeping is up to date including our HMDR and Pharmaceutical Policies and Procedures and that we adhere to these P&Ps. We have procedures in place in our ERP system to monitor the daily shipping of all products under our HMDR and wholesale licenses to ensure our Exemptees sign off before products are shipped.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A___. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:
N/A

Original Signature (electronic, copies or stamps not accepted)

1-5-26
Date

I, Kristina McIntosh_____, certify that as the designated representative for

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KM I am at least 21 years of age;
3. KM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kristina McIntosh
Print Name (First, Last)

K. McIntosh
Original Signature (electronic, copies or stamps not accepted)

1-5-26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristina McIntosh

Print Name (First, Last)

K. McIntosh

Original Signature (electronic, copies or stamps not accepted)

1/5/26

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Bernardino

I, Kristina Marie McIntosh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

K. McIntosh

Original Signature

1/5/26

Date

Subscribed and Sworn to before me this 5th day of January 2026

Notary Public Signature

HILDA NOEMI GORECKI
COMM. #2411440
Notary Public - California
San Bernardino County
My Comm. Expires July 25, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Schraders Medical Supply, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): MP00951

Physical Address: 5507 Brooks Street

City: Montclair State: CA Zip: 91763

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 9094477040 Website: www.schradersms.com

Licensing Company Email: kmcintosh@schradersms.com

Section 2: Personal Information

First: Marvinna Middle: M Last: McIntosh

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI[redacted] Sex ☐ M ☑ F ☐ X

Mailing Addres[redacted]

City: Upland State: CA Zi[redacted]

Telephone[redacted] Email: kmcintosh@schradersms.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California Lutheran University		01/1998 - 02/2000	
Address	**City**	**State**	**Zip**
60 W. Olsen Road	Thousand Oaks	CA	91360
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Cal Poly Pomona		06/1990-06/1992	
Address	**City**	**State**	**Zip**
3801 W. Temple Avenue	Pomona	CA	91768
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
Citrus College		06/1987 - 06/1989	
Address	**City**	**State**	**Zip**
1000 W. Foothill Blvd	Glendora	CA	91741
Diploma/Degree obtained, if any			
Associates of Science			

School Name		From - To (MM/YY – MM/YY)	
Danbury High School		1984 - 1987	
Address	**City**	**State**	**Zip**
3 Clapboard Ridge Rd	Danbury	CT	06811
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 - Current	[redacted]	Upland	CA	[redacted]
2018 - 2020	[redacted]	Claremont	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Schraders Medical Supply, Inc.			09/2008 - current	
Business Address		**City**	**State**	**Zip**
5507 Brooks Street		Montclair	CA	91763
Phone	**Title**			
909-447-7040	Vice President			
Description of Duties				
Managed all operations of the company				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NONE. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

NONE

Original Signature (electronic, copies or stamps not accepted)

10/9/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kristina McIntosh

Print Name (First, Last)

K McIntosh

Original Signature (electronic, copies or stamps not accepted)

10/10/2025

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of SAN BERNARDINO

I, KRISTINA M. McINTOSH, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

K McIntosh

Original Signature

10/10/2025

Date

Subscribed and Sworn to before me this 10TH day of OCTOBER 2025

L L Cortese

Notary Public Signature

L. L. CORTESE
COMM. # 2434341
NOTARY PUBLIC - CALIFORNIA
SAN BERNARDINO COUNTY
COMM. EXPIRES JAN. 15, 2027

(Seal)

KM

Employee Information Report

Please see the "Notes" tab for important information about this report

SCHRADERS' MEDICAL SUPPLY INC - 5520200

Current Active Employees

Reported by Insperity on: 01/06/26

First Name	Last Name	Job Title	Schedule
ALINE	AGAPITO	INCONTINENCE BILLING SUPERVISOR	M-F:7:00-3:30
ROBERTO	AGUSTIN	AR SPECIALIST	M-F:7:30-4:00
DOREEN	ALDERETE	MEDICARE AR SPECIALIST	M-F:7:00-4:00
VANESSA	AVILEZ MACIEL	WAREHOUSE- OVERNIGHT	M-F:9:00-5:30
ANDREW	AYALA	DRIVER	M-F:4:30-1:00
DAVID	AYALA	OPERATIONS SUPERVISOR	M-F:9:00-5:30
SYWKIA	BOLDEN	ENTERAL ACCOUNT REP	M-F:8:30-5:00
DONALD	BOLLAND	PURCHASING MANAGER	M-F:8:00-5:00
LISA	BOPF	WAREHOUSE	M-F:10:00-6:30
DEBRA	BRADY	BRANCH MANAGER	M-F:8:00-5:00
TYLER	BRADY	ENTERAL ACCOUNT REP	M-F:8:30-5:00
ABRAHAM	CAMPOS	WAREHOUSE - OVERNIGHT - FORKLIFT	M-F:10:00-6:30
JOSE	CARBAJAL-VASQUEZ	DRIVER	M-F:5:00-1:30
LILIA	CAYETANO	PUMP TECH	M-F:8:00-4:30
JENNIFER	CRIST	WAREHOUSE - OUR TRUCK - FORKLIFT	M-F:10:00-6:30
MARITES	DE VERA	CSR	M-F:8:30-5:00
TINA	GALARZA	MEDICARE INTAKE	M-F:8:00-5:00
EMILY	GARCIA	CUSTOMER SERVICE REP	M-F:8:00-5:00
LYDIA	GARCIA	CSR	M-F:8:00-5:00
CLEIDY	GENTRY	A/P MANAGER	M-F:6:00-2:30
ROBERT	GILES	PURCHASING AGENT	M-F:7:00-3:30
RUBY	GILL	ENTERAL ACCOUNT REP	M-F:8:00-4:30
SAMMY	GUTIERREZ	REPLENISHER/BACKUP DRIVER	M-F:10:00-6:30
EDUARDO	GUZMAN	OPERATIONS SUPERVISOR	M-F:4:00-12:30
DENISE	HERNANDEZ	ENTERAL ACCOUNT REP	M-F:8:00-5:00
CARMELA	HIGASHI	ENTERAL ACCOUNT REP	M-F:8:00-5:00
EVA	KIM	AR SPECIALIST	M-F:8:00-5:00
YOLIZTLI	LOPEZ	OPERATIONS MANAGER	M-F:8:00-5:00
ROBERT	LOZANO	ENTERAL ACCOUNT REP	M-F:8:00-5:00
MARIAH	LUNA	ADMINISTRATIVE ASSISTANT	M-F:8:00-5:00
MARIA	MANCENIDO	ENTERAL ACCOUNT REP	M-F:8:00-5:00
CARLOTA	MARTINEZ	MEDICARE AR SPECIALIST	M-F:6:30-3:30
DANIEL	MARTINEZ	LABORER AND HELPER	M-F:6:00-2:30

KRISTINA	MCINTOSH	PRESIDENT	
VERONICA	MENDOZA	ENTERAL ACCOUNT REP	M-F:8:00-5:00
ORALIA	MORALES	ENTERAL ACCOUNT REPRESENTATIVE	M-F:6:00-2:30
HUONG	NGUYEN	OUTSIDE SALES DIRECTOR	M-F:8:00-5:00
SONIA	OLMOS-SURA	MEDICARE BILLER	M-F:6:00-2:30
ERWIN	ONGCHANGCO	AUTHORIZATION COORDINATOR	M, Tu, F:8:00-5
ILENE	PALOMAREZ	CONTROLLER	M-F:8:00-5:00
ELENA	PENUNURI	AR SPECIALIST	M-F:8:00-5:00
JOSHUA	ROBERTS	WAREHOUSE - OVERNIGHT	M-F:9:00-5:30
MELODY	ROMERO	MEDICARE POSTING SPECIALIST	M-F:6:30-3:00
ALEXANDER	SANCHEZ	DRIVER	M-F:7:00-3:30
CARLOS	SANCHEZ	DRIVER	M-F:4:30-1:00
MARVIN	SCHRADER	EXECUTIVE ADVISOR	
KASSANDRA	SCOTT	CSR	M-F:8:30-5:30
MELANIE	SMITH	ENTERAL ACCOUNT REP	M-F:8:00-5:00
JOSE	SOTO	DRIVER	M-F:4:30-1:00
GRACE	SUIERVELD	ENTERAL ACCOUNT MANAGER/AUDITOR	M-F:8:00-5:00
ELCY MAE	TOMILLOSO	MEDICAL INTAKE COORDINATOR	M-F:8:00-5:00
KELLY	TROUTMAN	MEDICARE BILLING MANAGER	M-F:8:00-5:00
MARIBEL	URIBE	MEDICAL COORDINATOR	M-F:7:00-4:00
LETICIA	VALDEZ	CSR MANAGER	M-F:8:00-5:00
FRANCISCO	VALENCIA MACIEL	LABORER AND HELPER	M-F:9:00-5:30
JACQUELINE	VALENCIA	MEDI-CAL SUPPORT	M-F:9:00-5:30
MARIA	VASQUEZ	CSR	M-F:10:00-2:00
IRENE	VELARDE	MEDICARE BILLER	M-F:8:00-5:00
JORGE	VERA	WAREHOUSE - OVERNIGHT	M-F: 9:30-6:00
EVELYN	WHITE	INSIDE SALES	M-F:7:00-3:30
CEDRIC	WILSON	ENTERAL ACCOUNT REP	M-F:8:00-5:00

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☒ Hospital (# beds 30)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #:
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☒ Hospital
	PH		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Spring Mountain Sahara, an extension of Spring Valley Hospital

Physical Address: 5460 W Sahara Avenue

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-216-8900 Toll Free # (NAC 639.708, NRS 639.23286):

Fax: 702-322-1925 Contact Email: Denise.Cammann@uhsinc.com

Website: SpringMountainTreatmentCenter.com

Nevada Business License # (if applicable) ~~NEEDED~~ NV19981003340

Supervising/Managing Pharmacist Name (NRS 639.220): Denise Cammann

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 13339

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Denise Cammann	NV Pharmacist Registration #: 13339
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: -Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Universal Health Services, Inc.

Corporation/Organization Name: Valley Health System LLC

Mailing Address: 367 S Gulph Rd

City: King of Prussia State: PA Zip: 19406

Telephone: 610-768-3300 Email: uhscorpfilings@uhsinc.com

Contact Person Name: Steve Filton

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President (title) for Spring Mountain Sahara, an extension of (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Steve Filton

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

7/31/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Denise Cammann hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the managing pharmacist (title) for Spring Mountain (Sahara, an extension of Spring Valley Hospital) (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21st day of May, 20 25

Notary Public

Ambre Nicole Brown
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 23-3801-01
My Appt. Expires 06-08-2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Denise Cammann Pharmacist Registration #: 13339

Pharmacy Name: Spring Mountain Sahara, an extension of Spring Valley Hospital

Initial each statement below to indicate you have read and agree with the following:

DC I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

DC I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

DC I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

DC I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

DC I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	**Yes**	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	**State:**	**Date:**	**Case #:**

Criminal Action:	**State:**	**Date:**	**Case #:**	**County:**	**Court:**

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted) Date 9/4/25

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steve Filton

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/31/2025

Date

Board Use Only	Date Received: 11/10/25	Amount: 5000/CC

ATTACHMENT C
Officers and Directors of Valley Health System LLC

Name	Title	Business Address	% of Ownership
Edward Sim	President & Director (Director/Officer)	367 S Gulph Road King of Prussia, PA 19406-3121	0%
Steve G Filton	Vice President & Director (Director/Officer)	367 S Gulph Road King of Prussia, PA 19406-3121	0%
Matthew D. Klein	Secretary & Director (Director/Officer)	367 S Gulph Road King of Prussia, PA 19406-3121	0%
George H. Brunner, Jr.	Assistant Secretary (Officer)	367 S Gulph Road King of Prussia, PA 19406-3121	0%
Cheryl K. Ramagano	Treasurer (Officer)	367 S Gulph Road King of Prussia, PA 19406-3121	0%
Katharine M. Lyver	Assistant Treasurer (Officer)	367 S Gulph Road King of Prussia, PA 19406-3121	0%

ATTACHMENT B

Ownership Information on
Valley Health System LLC
d/b/a Spring Mountain Treatment Center

Name	Address	DOB	SSN/TIN	%ownership	Relationship
Alan B Miller	[redacted]	[redacted]		87.4% indirect	87.4% voting shares and stockholder in Universal Health Services, Inc.
Universal Health Services Inc.	367 S. Gulph Road King of Prussia PA 19406-3121	N/A	23-2077891	100% indirect	Sole shareholder in UHS Holding Company Inc.
UHS Holding Company Inc.	367 S. Gulph Road King of Prussia PA 19406-3121	N/A	23-2367472	100% indirect	Sole shareholder in Valley Hospital Medical Center Inc.
Valley Hospital Medical Center Inc.	367 S. Gulph Road King of Prussia PA 19406-3121	N/A	23-2117855	100% direct	Sole Member in Valley Health System LLC d/b/a Spring Mountain Treatment Center

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **VALLEY HEALTH SYSTEM LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/21/1998, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 05/30/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202505305766206
You may verify this certificate online at https://www.nvsilverflume.gov/home

FFN #20250429100601O filed 04/29/2025 09:03:43 AM by BAINUMJ - TR #2509591
Expires: 04/29/2030 - Page 1 of 1 - $25.00 - LYNN MARIE GOYA, COUNTY CLERK

REGISTERED BUSINESS ENTITY

Certificate of Assumed or Fictitious Name

Office of the Clark County Clerk

Lynn Marie Goya

Filing Type: ☒ New ☐ Renewal

This form is used by a registered business entity to file an assumed or fictitious name under which business will be conducted in Clark County, Nevada. A registered business entity is organized pursuant to the laws of Nevada that has filed formation documents with the Office of the Secretary of State; these entities are required to file an Annual List of Officers or its equivalent. For purposes of this form, these include domestic and foreign-qualified corporations, limited-liability companies, limited partnerships, limited-liability partnerships, and limited-liability limited partnerships.

Business Type: (select only one)

☐ Corporation ☒ Limited-Liability Company ☐ Limited Partnership ☐ Limited-Liability Partnership
☐ Limited-Liability Limited Partnership ☐ Professional Corporation ☐ Professional Association

Assumed or Fictitious Name: Spring Mountain Sahara, an extension of Spring Valley Hospital

Registered Business Entity: Valley Health System LLC
Exactly as it is registered (or intends to be registered) with the Nevada Secretary of State

Business Contact: (610) 768-3300 *Phone Number* uhscorpfilings@uhsinc.com *Email Address*

Mailing Address: 367 S Gulph Rd *Street Address* *Unit/Apt/Suite/Bldg*

King of Prussia *City* PA *State/Province* 19406 *Zip* USA *Country*

Print Authorized Signer Name: Steve Filton
Full Name (first middle last) of the person with signature authority for the registered business entity

Authorized Signer Signature: _____ **Date:** 4/22/2025

BY SIGNING ABOVE, EACH SIGNER DECLARES UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE STATE OF NEVADA THAT THE FOREGOING IS TRUE AND CORRECT. A FILED CERTIFICATE FOR AN ASSUMED OR FICTITIOUS NAME UNDER WHICH A BUSINESS IS BEING CONDUCTED IN CLARK COUNTY, NEVADA, IS VALID FOR FIVE (5) YEARS FROM THE FILING DATE.

Office use only – v7.27.23

Candy Nally

From: Cammann, Denise <Denise.Cammann@uhsinc.com>
Sent: Monday, February 2, 2026 12:15 PM
To: Candy Nally
Subject: Re: Nevada Pharmacy Application
Attachments: VALLEY HEALTH SYSTEM LLC (2).pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Please see attachment.
Thank you,

Denise Cammann
Pharmacy Director
Spring Mountain Treatment Center
Spring Mountain Sahara
Las Vegas, NV 89117
[redacted]

From: Candy Nally <cnally@pharmacy.nv.gov>
Sent: Wednesday, November 19, 2025 7:51 AM
To: Cammann, Denise <Denise.Cammann@uhsinc.com>
Subject: [EXTERNAL] Nevada Pharmacy Application

Spring Mountain Sahara, an extension of Spring Valley Hospital

We are in receipt of your pharmacy application. The required following documents were not included.

*Certificate of Corporate Status or Certificate of Good Standing from the Secretary of State's Office where the business is domiciled, dated within the last year.

All documents can be returned by email to cnally@pharmacy.nv.gov. Once received, we can continue the process of reviewing the application.
The next board meeting is scheduled for January 14-15, 2026 The deadline to receive documents is December 1.

If you have any questions, please feel free to contact us.

Thanks,

Candy M. Nally
Licensing Specialist
Nevada State Board of Pharmacy
cnally@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

UHS of Delaware, Inc. Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution of this information is prohibited, and may be punishable by law. If this was sent to you in error, please notify the sender by reply e-mail and destroy all copies of the original message.

STATE OF NEVADA

FRANCISCO V. AGUILAR
Secretary of State

RUBEN J. RODRIGUEZ
Deputy Secretary for Southern Nevada

2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2452

OFFICE OF THE
SECRETARY OF STATE

GABRIEL DI CHIARA
Chief Deputy Secretary of State

DEANNA L. REYNOLDS
Deputy Secretary for Commercial Recordings

401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7141

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

Work Order #: W2025053001632
May 30, 2025
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 40412

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Certificates	Fees	20254933154	5/30/2025 10:55:59 AM	Approved	1	$50.00	$50.00
Total							$50.00

Payments

Type	Description	Payment Status	Amount
Credit Card	7486277467576573603287	Success	$50.00
Credit Card	Service Fee	Success	$1.25
Total			$51.25

Credit Balance: $0.00

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH n/a	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Home Infusion, Specialty Pharmacy, and Enteral	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: BC6529157 ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Chartwell Pennsylvania, LP

Physical Address: 1001 Oakdale Road

City: Oakdale State: PA Zip: 15071-1502

Mailing Address (if different from physical address): n/a

City: n/a State: n/a Zip: n/a

Telephone: (412) 920-7500 Toll Free # (NAC 639.708, NRS 639.23286): (800) 755-4704

Fax: (412) 920-2830 Contact Email: Chartwell-Oakdale-Licensing@upmc.edu

Website: www.chartwellpa.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Alexander Ameredes

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24814

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Alexander Ameredes	NV Pharmacist Registration #: 24814
Name: n/a	NV Pharmacist Registration #: n/a
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials: n/a	%: n/a
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: n/a

Parent Company (if any): n/a

Corporation Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Date of SEC Registration: n/a	SEC Registration Number: n/a	Stock Exchange Symbol: n/a

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: n/a

Parent Company (if any): n/a

Corporation/Organization Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Chartwell Pennsylvania, LP

Mailing Address: 1001 Oakdale Road

City: Oakdale State: PA Zip: 15071-1502

Telephone: (412) 920-7500 Email: Chartwell-Oakdale-Licensing@upmc.edu

Contact Person Name: MaryLeigh Colbert, PharmD, Regulatory Compliance Pharmacy Manager

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☒ Yes ☐ No

Section 8: Sole Owner

Owner's Name: n/a

Business Name: n/a

Business Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director Pharmacy Operations (title) for Chartwell Pennsylvania, LP (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Alexander Ameredes, Director Pharmacy Operations

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

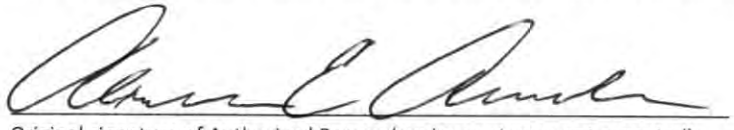
10/15/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexander Ameredes, Director Pharmacy Operations

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

10/15/25

Date

Board Use Only	Date Received: 10/20/25	Amount: $500 ck 1371

CHARTWELL Pharmacy

CHARTWELL PENNSYLVANIA, LP - OWNERSHIP						
	OWNER 1	**OWNER 2**	**OWNER 3**	**OWNER 4**	**OWNER 5**	**OWNER 6**
OWNER	UPMC COMMUNITY PROVIDER SERVICES	LIFE CARE HOME SERVICES OF NORTHWEST PENNSYLVANIA, LP	HERITAGE VALLEY HEALTH SYSTEM	UPMC WASHINGTON , F/K/A THE WASHINGTON HOSPITAL	BUTLER HEALTHCARE PROVIDERS	UPMC PRESBYTERIAN SHADYSIDE F/K/A UPMC PRESBYTERIAN UNIVERSITY HOSPITAL
		GREAT LAKES HOME HEALTHCARE SERVICES			BUTLER MEMORIAL HOSPITAL	
ADDRESS	200 LOTHROP ST FORBES TOWER #100558 PITTSBURGH, PA 15213-2536	1647 SASSAFRAS ST ERIE, PA 16502-1858	1000 DUTCH RIDGE RD BEAVER, PA 15009-9727	155 WILSON AVE WASHINGTON, PA 15301-3336	1 HOSPITAL WAY BUTLER, PA 16001	200 LOTHROP ST PITTSBURGH, PA 15213-2536
TIN	25-1804746	25-1536879	25-1441518	25-0965600	25-0965274	25-0965480
PHONE	(412) 647-9406	(814) 877-6120	(877) 771-4847	(724) 225-7000	(724) 283-6666	(412) 647-2345
FAX	(412) 647-3222	(814) 877-6032				
OWNERSHIP	77.73% DIRECT; 5/1/2007	4.75% DIRECT; 7/24/2014	4.75% DIRECT; 5/1/2015	4.98% DIRECT; 10/1/1996	2.85% DIRECT; 4/1/2015	4.94% DIRECT; 9/1/2020
OFFICER(S) & TITLE(S)	DEBORAH S. BRODINE, PRESIDENT	BRAD DINGER, CFO	NORMAN MITRY PRESIDENT/CEO	BROOK T. WARD, PRESIDENT	Thomas Albanesi, CFO	JARED WEINER, CFO
	REBECCA A. TAYLOR, VICE PRESIDENT					

CHARTWELL PENNSYLVANIA, LP - BOARD / EXECUTIVE LEADERSHIP		
OFFICER	**TITLE**	**ADDRESS & PHONE**
KATHLEEN PATRICK	PRESIDENT	1001 OAKDALE RD, OAKDALE, PA 15071; (412) 733-1910
EILEEN SIMMONS	SECRETARY/TREASURER	200 LOTHROP ST, FORBES TOWER, SUITE 11069, PITTSBURGH, PA 15235; (412) 647-8328
DAVID BENEDICT	COO	1001 OAKDALE RD, OAKDALE, PA 15071; (412) 733-1948

CHARTWELL PENNSYLVANIA, LP - OPERATIONAL LEADERSHIP		
NAME	**TITLE**	**ADDRESS & PHONE**
ALEXANDER E. AMEREDES	DIRECTOR, PHARMACY (OAKDALE)	1001 OAKDALE RD, SUITE 1, ROOM 110, OAKDALE, PA 15071; (412) 788-5654
OMIROS ROMEO ZACHARATOS	DIRECTOR, PHARMACY HM (ERIE)	380 E. BAYFRONT PKWY, SUITE #2, ERIE, PA 16507; (814) 874-3558
BRYAN ROBERT KUDLAWIEC	DIRECTOR, PHARMACY HM (ALTOONA)	1518 9TH AVE, ALTOONA, PA 16602; (814) 941-0106, EXT 6311520

Reviewed/Revised: September 4, 2025

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	CHARTWELL PENNSYLVANIA, L.P.
Request Type:	Subsistence Certificate
Request No.:	061276220
Receipt No.:	001973496
Filing Type:	Domestic Limited Partnership (LP/LLLP)
Filing Subtype:	Limited Partnership
Initial Filing Date:	December 29, 1999
Status:	Active

Issuance Date: July 31, 2025
File No.: 0002916064

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

CHARTWELL PENNSYLVANIA, L.P.

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Chartwell Pennsylvania, LP

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 1001 Oakdale Road

City: Oakdale State: PA Zip: 15071-1502

Mailing Address (if different from physical address): n/a

City: n/a State: n/a Zip: n/a

Telephone: (412) 920-7500 Website: www.chartwellpa.com

Licensing Company Email: Chartwell-Oakdale-Licensing@upmc.edu

Section 2: Personal Information

First: Alexander Middle: E. Last: Ameredes

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Duquesne University			08/1999 - 05/2005
Address	City	State	Zip
600 Forbes Avenue	Pittsburgh	PA	15282
Diploma/Degree obtained, if any			
PharmD			

School Name			From - To (MM/YY – MM/YY)
Weir High School			08/1995 - 05/1999
Address	City	State	Zip
100 Red Rid Road	Weirton	WV	26062
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
10/2008 to present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
UPMC Chartwell			02/2025 to present	
Business Address		**City**	**State**	**Zip**
1001 Oakdale Road		Oakdale	PA	15071
Phone	**Title**		**Number of Employed Hours**	
1-800-755-4704	Director of Pharmacy Operations		1200	

Description of Duties

As Director of Pharmacy Operations, I oversee all operational, regulatory, quality, and financial aspects of the Chartwell pharmacy services (specialty pharmacy, home infusion, enteral nutrition).

Business Name			From - To (MM/YY – MM/YY)	
Giant Eagle Inc			04/2003 - 09/2025	
Business Address		**City**	**State**	**Zip**
700 Cranberry Woods Drive		Cranberry Township	PA	16066
Phone	**Title**		**Number of Employed Hours**	
412-963-6200	Pharmacy District Manager		35,000	

Description of Duties

I oversaw and guided the operations of multiple pharmacy locations within a defined geographic district. I served as the bridge between leadership and store-level pharmacy teams, driving performance, compliance, and growth.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Alexander Elias Ameredes, **certify that as the designated representative for**

UPMC Chartwell,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AEA I am at least 21 years of age;
3. AEA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AEA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AEA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AEA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AEA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Alexander Ameredes

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/02/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexander Ameredes

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/25

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Allegheny

I, Marjorie H. Duerr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Marjorie H Duerr

Original Signature

10/15/2025

Date

Subscribed and Sworn to before me this 15 day of October.

Marjorie H Duerr

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Marjorie H. Duerr, Notary Public
Allegheny County
My commission expires October 13, 2026
Commission number 1427790
Member, Pennsylvania Association of Notaries

(Seal)

Chartwell Pennsylvania, LP
1-800-755-4704
1001 Oakdale Road, Oakdale PA, 15071
www.chartwellpa.com

10-16-2025

Personal History Application

The Personal History Application is not applicable to Chartwell Pennsylvania, LP ("Applicant"), as the partnership does not include any individual (or natural person) as owners. All ownership is held through a partnership consisting exclusively by corporate entities. The primary ownership is held under UPMC Community Provider Services at 77.73%. All other owners contain less than 10% of ownership. Please see the included ownership and board information.

Alexander Ameredes, Director Pharmacy Operations Date: 10-16-25

Commonwealth of Pennsylvania- Department of State
Bureau of Professional and Occupational Affairs

Mailing Address P.O. Box 2649, Harrisburg, PA 17105 Toll Free: 1-833-DOS-BPOA

CHARTWELL PENNSYLVANIA, LP
ALEXANDER ELIAS AMEREDES

License Number	: PP414443L	Initial License Date : 06/10/1991		Expiration Date	: 08/31/2027
License Type	: Pharmacy			License Status as of 8/5/2025	: Active
Issued By	: State Board of Pharmacy				
Address	: 1001 OAKDALE ROAD, OAKDALE, PA 15071				

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature of Licensee

SCAN ME

Please verify the license by visiting https://www.pals.pa.gov/verify or by scanning the QR Code

202508041573

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

10/30/2025

License Information

CHARTWELL PENNSYLVANIA, LP

1001 OAKDALE ROAD
OAKDALE, Pennsylvania 15071

Board/Commission:	State Board of Pharmacy	Status Effective Date:	03/14/2019
LicenseType:	Pharmacy	Issue Date:	06/10/1991
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2027
License Number:	PP414443L	Last Renewal:	08/04/2025
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
ALEXANDER ELIAS AMEREDES	Pharmacist Manager	Pharmacist	RP441696	Active	07/15/2025	09/30/2026

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BC6529157	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-05-2023

CHARTWELL PENNSYLVANIA
1001 OAKDALE RD
OAKDALE, PA 150711502

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BC6529157	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-05-2023

CHARTWELL PENNSYLVANIA
1001 OAKDALE RD
OAKDALE, PA 150711502

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Chartwell Pennsylvania, LP

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 1001 Oakdale Road

City: Oakdale State: PA Zip: 15071-1502

Mailing Address (if different from physical address): n/a

City: n/a State: n/a Zip: n/a

Telephone: (412) 920-7500 Toll Free # (NAC 639.708, NRS 639.23286): (800) 755-4704

Fax: (412) 920-2830 Contact Email: Chartwell-Oakdale-Licensing@upmc.edu

Website: www.chartwellpa.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Alexander Ameredes

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24814

Name of Designated Person(s) as defined by revised USP-797 guidelines: Alexander Ameredes

Email of Designated Person(s): ameredesae@upmc.edu

Telephone of Designated Person(s): (412) 920-7500

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 8/19/25

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Every Month

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked **"Yes"**, you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Section 2.11 attached

12. What laboratory performs your sterility or endotoxin testing?

Name: Children's Hospital of Pittsburgh Lab Department

Address: 4401 Penn Avenue, Floor 3

City: Pittsburgh State: PA Zip: 15224

Telephone: (412) 692-5831

13. What is your procedure for visual inspection of compounded sterile products?

Section 2.13 attached
PH 109 "Guidelines for Dispensing Products and Equipment
SOP: Standard Checking Process for Delivery slips
SOP: Mixing Report Documentation

14. How often do you perform glove fingertip and medial fill testing?

Initially and every six months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Section 2.15 attached
PH 200 Personnel Training and Education
Attachment Aseptic Technique in the Non-Hazardous Room Checklist

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Section 2.16 attached
PH 110 Cleaning and Disinfecting of the Compounding Area
SOP: Chartwell Pennsylvania, LP Oakdale Infusion Pharmacy Cleaning SOP
Attachment 3: Competency Assessment: Cleaning and Disinfecting Procedures

17. Who performs the sterile compounding process at your facility?

Pharmacists, Technicians, and Pharmacy Interns

18. Who is responsible and accountable for the sterile compounding process at your facility?

Pharmacist in Charge and Designated Person

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Section 2.19 attached
OPS056 Shipping and Cold Chain Management

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Baker Hoods		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No
9. If yes, list the name of the device: Spiros and B. Braun OnGuard		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Section 3.10 attached
Hazardous Drug Spill Procedure
Hazardous Medication Precautions
Patient Handbook pages 5, 9

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 3.11 attached
PH200 Personnel Training and Evaluation
Attachment Aseptic Technique in the Hazardous room checklist
OPS029 Disposal of Hazardous Materials Medical Waste
OPS030 Handling of Cytotoxic and Hazardous Agents

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

N/A

5. What is the frequency for completing surface sampling? N/A		
6. What is the frequency for using sporicidal agents? N/A		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexander Ameredes

Name of Person who Completed the Form

Director Pharmacy Operations

Title

Signature (copies or stamps not accepted)

10/15/25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

CHARTWELL Pharmacy

Chartwell Pennsylvania, LP
1-800-755-4704
1001 Oakdale Road, Oakdale PA, 15071
www.chartwellpa.com

Sterile Compounding Questionnaire

Section 2: Sterile compounding Questions

Question 11: List of sterile compounded products that you will be compounding for Nevada patients or consumers.

Description	STABLE_FOR	STABLE_STATE
Sterile Water for Injection 10ML IN 20ML SYRINGE	10	REFRIGERATED
Gammagard Liquid 10% <_> gm/<_> mL	10	REFRIGERATED
5-Fluorouracil <_>/258 mL NS Bag	9	REFRIGERATED
5mL Dextrose 5%Flush/12mL Syringe for Ambisome	10	REFRIGERATED
Ambisome 4mg/ml in SWFI Lock	10	REFRIGERATED
ceFAZolin 1 gm/10 mL SWFI in Syringe	10	REFRIGERATED
ceFAZolin 2 gm/20 mL SWFI in Syringe	10	REFRIGERATED
Blincyto 32.5 mcg/278 mL NSS (non-DEHP bag)	8	REFRIGERATED
Blincyto 65 mcg/280 mL NSS (non-DEHP bag)	8	REFRIGERATED
Blincyto 105mcg/162mL Bacteriostatic NSS (nonDEHP)	10	REFRIGERATED
Blincyto 130mcg/200mL Bacteriostatic NSS (nonDEHP)	10	REFRIGERATED
Blincyto 210mcg/110mL Bacteriostatic NSS (nonDEHP)	10	REFRIGERATED
Sodium Chloride 0.9% 15ml in 60ml syringe	10	REFRIGERATED
Cytarabine <_> mg in 275 NSS	4	ROOM TEMPERATURE
Sodium Chloride 0.9% 750ml	9	REFRIGERATED
Acyclovir 1000mg/250ml NSS (vial mate)	28	ROOM TEMPERATURE
500mg Ambisome/500ml D5W	10	REFRIGERATED
13gm Ampicillin /650ml 0.9% NaCl	3	REFRIGERATED
Ampicillin 9gm/450ml 0.9% NaCl	3	REFRIGERATED
Avycaz 2.5 gm/250 mL 0.9% NaCl Vial Mate (1.25 gm)	28	ROOM TEMPERATURE
50MG Caspofungin/250ml 0.9% NaCl	30	REFRIGERATED
70mg Caspofungin/250ml 0.9% NaCl	30	REFRIGERATED
ceFAZolin 7 gm/350 mL NS Bag	10	REFRIGERATED
Cefepime 1.25 gm/62.5 mL NS Bag	10	REFRIGERATED
Cefepime 3.5 gm/175 mL NS Bag	10	REFRIGERATED
Cefepime 2.25 gm/112.5 mL NS Bag	10	REFRIGERATED
Cefepime 7 gm/350 mL NS Bag	10	REFRIGERATED
CefOXitin <_> mg/<_> mL Bag	10	REFRIGERATED
200mg Ciprofloxacin / 100ml 5% Dextrose	10	REFRIGERATED
Ganciclovir(DHPG)___mg/100ml 0.9% NaCl	9	REFRIGERATED
DOBUTamine <_> mg/<_> mL D5W Bag	10	REFRIGERATED

Description	STABLE_FOR	STABLE_STATE
CeFAZolin 5mg/mL in NSS Lock	7	REFRIGERATED
CefOXitin 1 gm/10 mL SWFI in Syringe	10	REFRIGERATED
CefOXitin 2 gm/20 mL SWFI in Syringe	10	REFRIGERATED
CefTAZidime 2mg/mL in NSS Lock	3	ROOM TEMPERATURE
1gm Ertapenem/50ml 0.9% NaCl MBP	15	ROOM TEMPERATURE
levETIRAcetam (Keppra) 500mg/100ml NSS MB+	15	ROOM TEMPERATURE
Ketamine (Ketalar) 1000mg/100ml	4	ROOM TEMPERATURE
LevoFLOXacin 250 mg/50 mL 5% Dextrose Bag	10	REFRIGERATED
LevoFLOXacin 750 mg/150 mL 5% Dextrose Bag	10	REFRIGERATED
Cefepime 1gm/50ml NSS	10	REFRIGERATED
Cefepime 2gm/50ml NSS	7	REFRIGERATED
Milrinone 20mg/100ml 5% Dextrose	10	REFRIGERATED
Nafcillin 13gm/650ml 0.9% NaCl	10	REFRIGERATED
Oxacillin 13gm/325ml 0.9% NaCl	7	REFRIGERATED
Penicillin Potassium 13 MU/130 mL 0.9% NaCl	7	REFRIGERATED
Penicillin Sodium 25 MU/500 mL NS Bag	10	REFRIGERATED
CefTRIAXone 1 gm/50 mL 0.9% NaCl in Bag	10	REFRIGERATED
CefTRIAXone 2 gm/50 mL 0.9% NaCl in Bag	10	REFRIGERATED
Synercid 500mg/250ml D5W vial mate	28	REFRIGERATED
Treprostinil __ mg/50 mL High-pH Diluent	9	REFRIGERATED
DAPTOmycin <_> mg/<_> mL NS in Syr	10	REFRIGERATED
13.5GM AMPICILLIN-SULBACTAM/450ML	3	REFRIGERATED
Ampicillin-Sulbactam 10.5 gm/350 mL NS Bag	3	REFRIGERATED
Vancomycin CI 7.5gm/1500ml NSS	7	REFRIGERATED
Midazolam 250 mg/250 mL NSS	10	ROOM TEMPERATURE
200mg Voriconazole/50ml NSS MBP	15	ROOM TEMPERATURE
cycloPHOSphamide _____mg/250 mL NSS	6	REFRIGERATED
500mg Azithromycin/250ml 0.9% NaCl	7	REFRIGERATED
Piperacillin-Tazobactam 19.25 gm/214 mL NS Bag	7	REFRIGERATED
Piperacillin-Tazobactam 15 gm/167 mL NS Bag	7	REFRIGERATED
Piperacillin-Tazobactam 12.94 gm/144 mL NS Bag	7	REFRIGERATED
Dextrose 5% in Water 5 mL Flush in Syringe	10	REFRIGERATED
5mL Dextrose 5%FLUSH/ 12 mL syringe for DALVANCE	10	REFRIGERATED
DAPTOmycin 5mg/mL in Lactated Ringers Lock	10	REFRIGERATED
5 mL Dextrose 5% FLUSH/12 mL syringe	10	REFRIGERATED
HYDROmorphone 1000 mg/100 mL Cassette	10	REFRIGERATED
HYDROmorphone 100 mg/100 mL NSS Cassette	10	REFRIGERATED
Doripenem 500mg/100ml 0.9% NaCl MB+	15	ROOM TEMPERATURE
DOXOrubicin ____mg/____mL in a 35 mL syringe	14	REFRIGERATED
Vancomycin 1 gm/250 mL 0.9% NaCl	10	REFRIGERATED
Vancomcyin 750 mg/250 mL 0.9% NaCl	10	REFRIGERATED
Acyclovir <_>mg/<_>mL NS Elastomeric 100mL-50mL/hr	4	ROOM TEMPERATURE
Acyclovir <_>mg/<_>mL NS Elastomeric 50mL-50mL/hr	4	ROOM TEMPERATURE
Ampicillin 2gm/100mL NS Elastomeric 100mL-200mL/hr	3	REFRIGERATED
ceFAZolin 1 gm/60mL NS Elastomeric 50 mL-50 mL/hr	10	REFRIGERATED

Description	STABLE_FOR	STABLE_STATE
ceFAZolin 2 gm/120mL NS Elastomeric 100mL-100mL/hr	10	REFRIGERATED
Azithromycin 500 mg/250 mL NS Elastomeric	7	REFRIGERATED
Aztreonam 1 gm/100 mL NS Elastomeric	7	REFRIGERATED
Aztreonam 2 gm/100 mL NS Elastomeric	7	REFRIGERATED
Caspofungin 50mg/100mL NS elasto 100mL-100mL/hr	10	REFRIGERATED
CefOXitin 1 gm/100 mL NS Elastomeric	7	REFRIGERATED
CefOXitin 2 gm/200 mL NS Elastomeric	7	REFRIGERATED
DAPTOmycin <_>mg/<_>mL NS Elasto 100mL-200mL/hr	10	REFRIGERATED
DAPTOmycin <_> mg/50mL NS Elastomeric 50mL-50mL/hr	10	REFRIGERATED
Gentamicin <_> mg/<_> mL NS Elastomeric	7	REFRIGERATED
1GM Ertapenem /100ml NS Elastomeric 100ml-100ml/hr	7	REFRIGERATED
500mg Ertapenem/50mL NS Elastomeric 50mL -50mL/hr	7	REFRIGERATED
1gm Cefepime/50mL NS Elastomeric 50mL - 50mL/hr	10	REFRIGERATED
2gm Cefepime/100mL NS Elastomeric 100mL - 100mL/hr	10	REFRIGERATED
Meropenem 1 gm/200mL NS Elastomeric 250mL-250mL/hr	10	REFRIGERATED
Meropenem 2gm/400mL NS Elastomeric 400 mL-200mL/hr	10	REFRIGERATED
Micafungin 100 mg/100 mL NS Elastomeric	4	REFRIGERATED
Micafungin 150 mg/100 mL NS Elastomeric	4	REFRIGERATED
Nafcillin 12gm/240mL NS Elastomeric 270mL-10mL/hr	10	REFRIGERATED
For Enjaymo 0.9% Sodium Chloride 370 mL Bag	10	REFRIGERATED
For Enjaymo 0.9% Sodium Chloride 350 mL Bag	10	REFRIGERATED
12gm Oxacillin/120ml NS Elastomeric 125ml-5ml/hr	8	REFRIGERATED
Piperacillin-Tazobactam <_>gm/240mL NS Elastomeric	10	REFRIGERATED
DOXOrubicin_/Etoposide_/VinCRIStine_mg in 1050 mL	3	ROOM TEMPERATURE
Imipenem-Cilastatin 1000 mg/200 mL NS Elastomeric	3	REFRIGERATED
Imipenem-Cilastatin 250 mg/50 mL NS Elastomeric	3	REFRIGERATED
Imipenem-Cilastatin 500 mg/100 mL NS Elastomeric	3	REFRIGERATED
CefTRIAXone 1gm/50mL NS Elastomeric 50 mL-50 mL/hr	10	REFRIGERATED
CefTRIAXone 2gm/50mL NS Elastomeric 50 mL-50 mL/hr	10	REFRIGERATED
MethylPREDNISolone (SOLU-Medrol) 1gm/100mL NS Ela	7	REFRIGERATED
1GM Tobramycin/100mL NS Elastomeric 100mL-100mL/hr	10	REFRIGERATED
500mg Tobramycyin/50mL NS Elastomeric 50mL-50mL/hr	10	REFRIGERATED
1.25GM Vancomycin/250ml NS Elasto 250ml-175ml/hr	10	REFRIGERATED
1.5Gm Vancomycin/300ml NS Elasto 400ml-200ml/hr	10	REFRIGERATED
1GM Vancomycin/250ml NS Elastomeric 250ml-250ml/hr	10	REFRIGERATED
2GM Vancomycin/400ml NS Elasto 400ml-200ml/hr	10	REFRIGERATED

Description	STABLE_FOR	STABLE_STATE
500mg Vancomycin/100ml NS Elasto 100ml-100ml/hr	10	REFRIGERATED
750mg Vancomycin/150mL NS Elasto 100ml-100ml/hr	10	REFRIGERATED
Zerbaxa 1.5 gm/100 mL NSS Elasto 100mL-100mL/hr	8	REFRIGERATED
Zerbaxa 3gm/250mL NSS elastomeric 250mL-250mL/hr	8	REFRIGERATED
Piperacillin-Tazobactam 2.25 gm/50 mL NSS Elasto	10	REFRIGERATED
Piperacillin-Tazobactam 3.375 gm/50 mL NSS Elasto	10	REFRIGERATED
Piperacillin-Tazobactam 4.5 gm/50 mL NSS Elasto	10	REFRIGERATED
__mg Famotidine/__ml SWFI/12ml Syringe	10	REFRIGERATED
1 gm ceFAZolin/10 mL SWFI in 50 mL Syringe	10	REFRIGERATED
2 gm ceFAZolin/20 mL SWFI in 50 mL Syringe	10	REFRIGERATED
Cefotaxime 1 gm/20 mL SWFI in a 50 mL SYRINGE	10	REFRIGERATED
Clindamycin 300 mg/15 mL SWFI in 50 mL syringe	4	ROOM TEMPERATURE
Clindamycin 600 mg/30 mL SWFI in 50 mL syringe	4	ROOM TEMPERATURE
Clindamycin 900 mg/45 mL SWFI in 50 mL syringe	4	ROOM TEMPERATURE
DAPTOmycin <_> mg/50 mL NSS in Syringe	10	REFRIGERATED
DAPTOmycin <_> mg/10 mL NSS in Syringe	10	REFRIGERATED
DAPTOmycin <_> mg/20 mL NSS in Syringe	10	REFRIGERATED
Ganciclovir(DHPG)___mg/50ml 0.9%NaCl	9	REFRIGERATED
Ganciclovir(DHPG)____mg/50ml 0.9% NaCl	9	REFRIGERATED
CefTAZidime 1 gm/10 mL SWFI in 50 mL Syringe	7	REFRIGERATED
CefTAZidime 2 gm/20 mL SWFI in 50 mL Syringe	7	REFRIGERATED
Cefepime 1 gm/10 mL SWFI in 50 mL Syringe	10	REFRIGERATED
Cefepime 2 gm/20 mL SWFI in 50 mL Syringe	10	REFRIGERATED
CefTAZidime (Fortaz) 1 gm/10 mL SWFI in Syringe	7	REFRIGERATED
CefTAZidime (Fortaz) 2 gm/20 mL SWFI in Syringe	7	REFRIGERATED
CefTRIAXone 1 gm/10 mL SWFI in 50 mL Syringe	10	REFRIGERATED
CefTRIAXone 2 gm/20 mL SWFI in 50 mL Syringe	10	REFRIGERATED
Tobramycin <_> mg/50 mL NSS in Syringe	10	REFRIGERATED
Vancomycin 750 mg/50 mL NSS (2 x 750 mg syringes)	9	REFRIGERATED
Vancomycin 875mg/50mL NSS (2x 875mg syringes)	9	REFRIGERATED
Vancomycin 1250mg/50ml NSS in syringe	9	REFRIGERATED
Vancomycin 750 mg/50mL NSS (2 x 750 mg syringes)	9	REFRIGERATED
Vancomycin 1 gm/50 mL NSS in Syringe	9	REFRIGERATED
Vancomycin 1 gm/50 mL NSS (2 x 1 gm syringes)	9	REFRIGERATED
Vancomycin 500 mg/50 mL NSS in a syringe	9	REFRIGERATED
Vancomycin 750mg/50ml NSS in a syringe	9	REFRIGERATED
Vancomycin 1gm / 50ml NSS in a syringe	9	REFRIGERATED
1.5GM CEFUROXIME/30ML NSS IN A 50ML SYRINGE	10	REFRIGERATED
750MG CEFUROXIME/15ML NSS IN A 50ML SYRINGE	10	REFRIGERATED
Piperacillin-Tazobactam 2.25 gm/10 mL NS in Syr	7	REFRIGERATED
Piperacillin-Tazobactam 3.375 gm/15 mL NS in Syr	7	REFRIGERATED
Piperacillin-Tazobactam 4.5 gm/20 mL NS in Syr	7	REFRIGERATED
Acyclovir __mg/__mL NS in a Bag	4	ROOM TEMPERATURE
1gm Ampicliin /50ml 0.9% NaCl MBP	15	ROOM TEMPERATURE
1gm Ampicillin /50ml 0.9% NaCl MBP	15	ROOM TEMPERATURE

Description	STABLE_FOR	STABLE_STATE
2gm Ampicillin /100ml 0.9% NaCl MBP	15	ROOM TEMPERATURE
1gm ceFAZolin/50ml 0.9% NaCl	10	REFRIGERATED
1gm ceFAZolin / 50ml 0.9% NaCl	10	REFRIGERATED
2gm ceFAZolin / 100ml 0.9% NaCl	10	REFRIGERATED
Avycaz 2.5 gm/250 mL 0.9% NaCl Vial Mate	28	ROOM TEMPERATURE
1gm Aztreonam /50ml 0.9% NaCl	7	REFRIGERATED
2gm Aztreonam /100ml 0.9% NaCl	7	REFRIGERATED
Colistin (Colistimethate Na) 150 mg/100 mL NS MB+	15	ROOM TEMPERATURE
Cresemba 372mg/250ml 0.9% NaCl vial mate	28	REFRIGERATED
DAPTOmycin <_> mg/50 mL 0.9% NaCl	10	REFRIGERATED
Doxycycline 100mg/100ml NSS MB+	15	ROOM TEMPERATURE
Gentamicin 1mg/ml in NSS Lock	3	ROOM TEMPERATURE
Ertapenem 1 gm/50 mL NS MB+	15	ROOM TEMPERATURE
Ertapenem 500mg/50ml NSS	6	REFRIGERATED
Cefepime 1gm/50ml 0.9% NaCl	10	REFRIGERATED
Cefepime 2gm/50ml 0.9% NaCl	7	REFRIGERATED
Meropenem 1 gm/100 mL NS MB+	15	ROOM TEMPERATURE
Meropenem 500 mg/50 mL NS MB+	15	ROOM TEMPERATURE
Micafungin 100 mg/100 mL NS MB+	15	ROOM TEMPERATURE
Imipenem/Cilastin 2x500mg/100ml NaCl MBP	15	ROOM TEMPERATURE
Imipenem/Cilastin 250mg/100ml NaCl MBP	15	ROOM TEMPERATURE
Imipenem/Cilastin 500mg/100ml NaCl MBP	15	ROOM TEMPERATURE
rifAMPin 600mg/100ml 5% Dextrose MBP	15	ROOM TEMPERATURE
400mg Teflaro (Ceftaroline)/100mL 0.9% NaCl MBP	15	ROOM TEMPERATURE
600mg Teflaro (Ceftaroline)/100mL 0.9% NaCl MBP	15	ROOM TEMPERATURE
Tygacil (Tigecycline) 50 mg/100 mL NSS MB+	30	ROOM TEMPERATURE
1.5GM AMPICILLIN/SULBACTAM/50ML 0.9%NACL MBP	15	ROOM TEMPERATURE
3GM AMPICILLIN/SULBACTAM/100ML 0.9%NACL MBP	15	ROOM TEMPERATURE
Lacosamide (Vimpat) 200mg/50ml NSS MB+	15	ROOM TEMPERATURE
Voriconazole (Vfend) <_> mg/<_> NS Bag	10	REFRIGERATED
Zerbaxa 1.5gm/100ml 0.9% NaCl MB+	15	REFRIGERATED
Zerbaxa 1.5gm/100ml NSS	7	REFRIGERATED
Zerbaxa 150mg/100ml NSS	7	REFRIGERATED
Zerbaxa 375mg/100ml NSS	7	REFRIGERATED
Zerbaxa 750mg/100ml NSS	7	REFRIGERATED
Zometa 4mg/100ml 0.9% NaCl+	30	ROOM TEMPERATURE
2.25gm Piperacillin-Tazobactam/50ml 0.9% NaCl	10	REFRIGERATED
3.375gm Piperacillin-Tazobactam/50ml 0.9% NaCl	10	REFRIGERATED
4.5gm Piperacillin-Tazobactam/50ml 0.9% NaCl	10	REFRIGERATED
MG CYTARABINE(ARA-C)/ ML SWFI IN 10ML SYRINGE	7	REFRIGERATED
Ifosfamide _____mg in 500 mL NSS (TV=___mL)	10	REFRIGERATED
Jelmyto 68mg/17ml Vial	4	ROOM TEMPERATURE
Leucovorin ____mg in 250 mL D5W (TV=_____mL)	14	ROOM TEMPERATURE
Cefepime (Maxipime) 1gm in 10ml SWFI syringe	10	REFRIGERATED
Cefepime (Maxipime) 2gm in 20ml SWFI syringe	10	REFRIGERATED

Description	STABLE_FOR	STABLE_STATE
Morphine 1000mg/100mL NSS cassette	10	REFRIGERATED
Morphine 100mg/100mL NSS in cassette	10	REFRIGERATED
ceFAZolin 2 gm/20 mL SWFI in a Syringe	10	REFRIGERATED
ceFAZolin 3 gm/30 mL SWFI in a Syringe	10	REFRIGERATED
600mg Clindamycin / 100ml 0.9% NaCl	10	REFRIGERATED
900mg Clindamycin / 100ml 0.9% NaCl	10	REFRIGERATED
1.5 GM Vancomycin/300mL NSS Dial-a-Flo	9	REFRIGERATED
1GM Vancomycin/250mL NSS Dial-A-Flo	9	REFRIGERATED
*compounded*For Nexviazyme* Dextrose 5% <_>mL*	10	REFRIGERATED
*Compounded*For Nexviazyme* Dextrose 5% 50mL Flush	10	REFRIGERATED
Omegaven in Empty EVA bag <_>gm/ <_>mL	6	REFRIGERATED
<_>(InFLIXimab-<_>) *HOME MIX* <_> mg	180	REFRIGERATED
Blincyto <_>mcg/270mL NSS (non-DEHP bag)	8	REFRIGERATED
Blincyto <_>mcg/110mL Bacteriostatic NSS (nonDEHP)	10	REFRIGERATED
For Venofer Sodium Chloride 0.9% <_>mL	10	REFRIGERATED
40MG PROTONIX/100ML 0.9% NACL(MINI-BAG +)	14	ROOM TEMPERATURE
Rituxan ____mg/____mL NSS	2	REFRIGERATED
for RiTUXimab 0.9% NaCl 400 mL Bag	10	REFRIGERATED
CefTRIAXone (Rocephin) 1 gm/10 mL SWFI in Syringe	10	REFRIGERATED
CefTRIAXone (Rocephin) 2 gm/20 mL SWFI in Syringe	10	REFRIGERATED
SOLU-Medrol <_>mg/<_>mL 0.9% NaCl in Syringe	10	REFRIGERATED
Solu-CORTEF (Hydrocortisone) <_>mg/<_>mL NSS syr	10	REFRIGERATED
Cytarabine <_> mg/<_> mL SWFI PF Syr	10	REFRIGERATED
Cytarabine <_> mg/<_> mL Bacteriostatic Water Syr	10	REFRIGERATED
Telavancin (Vibativ) _mg/_mL 0.9% NaCl	10	REFRIGERATED
Heparin <_> units in <_> ml in a syringe	9	REFRIGERATED
for use with Tzield 0.9% NaCl 18 mL Vial	10	REFRIGERATED
for use with Tzield 0.9% NaCl 25 mL Syr	10	REFRIGERATED
Vancomycin 5mg/ml in NSS Lock	10	REFRIGERATED
vinBLAStine ____mg/____mL in a 30mL syringe	14	ROOM TEMPERATURE

Chartwell Pennsylvania, LP
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Sterile Compounding Questionnaire

Section 2: Sterile Compounding Questions

Question 13: What is your procedure for visual inspection of compounded sterile products?

- *See attached policies*
  - *PH109 "Guidelines for Dispensing Products and Equipment*
  - *SOP: Standard checking process for delivery slips*
  - *SOP: Mixing Report Documentation*

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

CHARTWELL Pharmacy

TITLE: GUIDELINES FOR DISPENSING PRODUCTS AND EQUIPMENT	POLICY NUMBER: PH109
URAC STANDARDS: N/A	ACHC STANDARDS: DRX5-1A, DRX7-8J, DRX7-8J.01, DRX7-8Q.02, DRX7-9B, DRX7-12A, DRX7-12E
TJC STANDARDS: MM.05.01.11 EP 1, 2, 3, 4; PC.02.01.03 EP 11; MC.03.08.03 EP 1, 2, 3.	
EFFECTIVE DATE: 1/1/2021	REVISION DATE: 9/1/21, 11/1/23, 11/1/24, 5/1/25
REVIEWED DATE: 5/1/2021, 5/1/22, 11/1/23, 11/1/24, 5/1/25	APPROVAL AUTHORITY: KATHLEEN PATRICK, PRESIDENT

I. POLICY

All drugs, ancillary supplies, and infusion equipment will be dispensed according to applicable law and regulation, under the direction and oversight of a pharmacist. The organization assures pharmaceuticals are maintained under appropriate conditions during deliveries, in accordance with manufacturer and USP <797> and <800> requirements.

II. PROCEDURES

A. Non-Compounded Products:

1. All non-compounded legend drugs must be checked by a pharmacist prior to being dispensed for a patient.

2. The drug will be checked:

    a. For NDC, lot number, and expiration date
    b. For the accuracy and completeness of the label

3. The pharmacist will document the accuracy of the filled prescription by signing the delivery ticket/mixing report, unless otherwise required by applicable law and regulation.

4. All non-compounded legend drugs, once labeled, will be stored under appropriate storage conditions within the pharmacy until dispensed for a patient.

5. Lot numbers, manufacturer, and expiration dates must be recorded on a non-compounded form or on the delivery ticket/mixing report.

B. Compounded Products:

1. The final product will be checked by the pharmacist against the original prescription, compounding report, and items used for compounding to verify its accuracy and completeness.

2. All compounded products will undergo a visual inspection of the final product at the completion of compounding and before dispensing should the CSP not be released on the day of preparation.

    a. Physical appearance is expected to be free of inappropriate visible particulates, free of foreign matter, free of discoloration, free of any other defects
    b. Visual inspection includes an assessment that the CSP does not exhibit any defects such as precipitation, cloudiness, or leakage of the container.
    c. Should a product be rejected during visual inspection, it must be labeled as such and segregated from active stock.

3. Whenever possible, the final product will be double checked by another pharmacist, technician, or nurse.

4. The pharmacist will document the accuracy of the final product by signing and initialing the compounding record, unless otherwise required by applicable law and regulation.

5. The pharmacist will review and verify the accuracy and completeness of the labels. Compounded products may be labeled by the pharmacy technicians if allowed by law and regulation. If allowed, pharmacy technicians must initial the labels.

6. All labeled units will be retained under appropriate storage conditions until ready to be packaged and delivered.

7. A pharmacist must check all compounded products prior to being dispensed to a patient.

C. Supplies:

1. It will be a joint responsibility between pharmacy and nursing and other appropriate staff for communicating with the patient to determine the supplies necessary for a patient's care. Supplies may be gathered by non-clinical staff.

2. A nurse may verify the dispensing of supplies if there are no prescription items involved.

D. Equipment:

1. As required by applicable law, prescriptions will be obtained and filed for all equipment dispensed to a patient.

2. Prior to dispensing, the pharmacist is responsible for:

    a. Participating in the selection of the pump to be used along with the other clinicians.

b. Ensure the preventative maintenance sticker is appropriately attached to the pump and dated within the past 90 days to reflect DME's completion of the appropriate cleaning, Routine and Preventative Maintenance, and Safety and Performance Testing.
c. Ensuring that all infusion pumps are accurately programmed prior to being dispensed
d. Communicating all pump parameters to the nursing staff

3. In the event of an equipment malfunction that may threaten the health of the patient, provisions will be made to be able to provide maintenance, replacement, or utilize a back-up system to resolve the problem within a reasonable time of notification.

E. Dispensing Procedure:

1. When dispensing the final products:

a. A delivery/packing slip will be generated by the automated information system, for all pharmacy service products/supplies and/or DME equipment.
b. The delivery ticket/packing slip may be manually generated if the automated information system is inoperable (ie. emergency situations).
c. All drugs and supplies will be gathered and checked against the delivery ticket to ensure that the correct items are being sent and that no item has been omitted.
d. Validate NDC of all non-compounded products and initial the delivery ticket by the appropriate prescription.
e. All orders will be checked by a pharmacist or nurse or double-checked by delivery or other staff prior to leaving the building.

2. In cases of back orders or shortages, all appropriate providers will be notified, and the pharmacist will document this in the progress notes.

3. Medications are dispensed in a timely manner as defined by the organization to meet patient needs.

4. Medications are dispensed in a form that minimizes the need for additional mixture or preparation, when possible.

5. The organization dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice.

F. Packaging and Delivery Considerations:

1. Procedures for packaging, handling, and transporting CSPs are developed by compounding staff in collaboration with other departments' staff involved in CSP functions. Non-compounding staff are monitored to manage consistent implementation of procedures.

2. All drug products will be packaged in an appropriate manner so that the dispensing pharmacist is assured of the stability and integrity of the product during delivery:

a. Coolers will be used for refrigerated pharmaceuticals.
1) Infusion pharmacy products will be packaged in a Styrofoam cooler with ice packs

2) Select products (Specialty Pharmaceuticals) will be packaged in a Propak cooler with ice packs.
3) CSPs are visually inspected to ensure the integrity of the container closure system to be free from leakage, crack or improper seals.

b. Appropriate packaging precautions will be taken to protect the product from excessive motion that could result in the breakage, leakage, or alteration of the product during transport.
c. Cytotoxic and hazardous drugs must be contained in a clearly labeled zipper-lock bag and placed in a similarly labeled rigid container prior to delivery.
d. All packages delivered by staff will be labeled with the name of the patient.
e. All staff delivering cytotoxic or hazardous drugs must have a chemo spill kit available in the event of a chemo spill.
f. All packages delivered by a courier service will be labeled with the name and address of the patient, as well as any precautionary labels.

3. The delivery slip will be included with the package and the patient/caregiver will sign the delivery ticket/ packing slip upon receipt of drug, supplies and/or equipment and a copy is provided to the patient/caregiver, whenever possible.
4. The original delivery ticket/packing slip will be returned to the office, confirmed as correct, then filed in the patient's clinical record.
5. For packages delivered via third party carrier (i.e. UPS) the tracking number and delivery confirmation may be used in lieu of a signed delivery slip. per payor or contractual requirements

III. APPROVAL HISTORY

Approved By:	Title:	Date:
Kathleen Patrick	President	01/01/2021
Kathleen Patrick	President	05/01/2021
Kathleen Patrick	President	09/01/2021
Kathleen Patrick	President	05/01/2022
Kathleen Patrick	President	11/01/2023
Kathleen Patrick	President	11/01/2024
Kathleen Patrick	President	05/01/2025

Standard Operating Procedure

Effective: October 2023

Title: Standard checking process for Delivery slips

Objective: Provide accountability of tasks completed

a. To provide consistency to ensure the documentation is interpreted correctly by all staff involved in the dispensing process.
b. To provide a quick visual double check to verify all items on the delivery slip are sent.
c. To assign accountability during all steps of the process.
d. To ultimately decrease medication errors

Procedure:

The pharmacist will utilize HCN initials on the delivery slip.

Warehouse assistant

1. Add a check mark "✓" on the line under QTY delivered once the supply is picked which is acknowledgement that the supplies are in the delivery.

Initial in the appropriate sign off area.

MEDICATIONS

Rx #	Description	Qty Ord	Qty Deliv	Lot #	Exp Date
477133-0	LACTATED RINGERS 660 mL + Additives	7			
444935-42	1-61-843 10ml 0.9% Sodium Chloride/12ml Syringe	20 @ 1 EA	✓	ABXR7	4/20/5
444936-44	1-28-232 50 Units Heparin/5ml in 12ml syringe(10uni...	8 @ 1 EA	✓	12345	4/20/5

SUPPLIES

Code	Bin	Description	Qty Ord	Qty Deliv
5-90-114		BATTERY DURACELL COPPERTOP ALKALINE 9V	3 EA	✓
3-11-211	WC3A	CADD PRIZM HI VOLUME SET 21 7357V	7 EA	✓
3-18-160	WC4D	MICROCLAVE INJECTION CAP (B3300)	1 EA	
3-54-219	WE3A	DRESSING CHANGE KIT (MSDC 009963)	1 EA	✓

RETURNABLE EQUIPMENT AGREEMENT: I understand that I have received this equipment in good condition. I will return the equipment in good condition upon completion of therapy by contacting Chartwell Pennsylvania at 1-800-755-4704.

PICKED BY: STP CHECKED BY: _____/_____ PACKED BY: _____

Pharmacist

1. When checking supplies, will add a slash in the opposite direction at the top of the check mark "\" making an "X". This is acknowledgement that the correct supplies are in the delivery.
2. If something is missing put a circle in the QTY delivered column.
3. Initial in the appropriate sign off area.

Rx #	Description	Qty Ord	Qty Deliv	Lot #	Exp Date
477133-0	LACTATED RINGERS 660 mL + Additives	7			
444935-42	1-61-843 10ml 0.9% Sodium Chloride/12ml Syringe	20 @ 1 EA	X	Black2	4/20/19
444936-44	1-28-232 50 Units Heparin/5ml in 12ml syringe(10uni...	8 @ 1 EA	X	12345	4/20/19

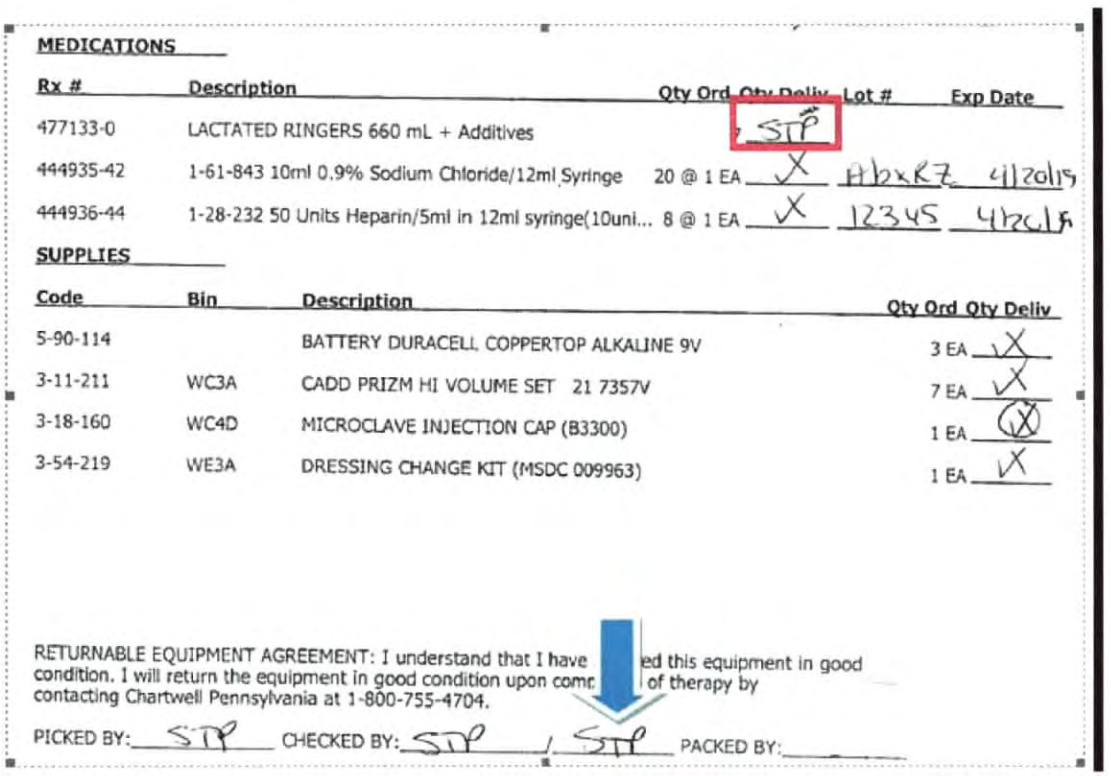
SUPPLIES

Code	Bin	Description	Qty Ord	Qty Deliv
5-90-114		BATTERY DURACELL COPPERTOP ALKALINE 9V	3 EA	X
3-11-211	WC3A	CADD PRIZM HI VOLUME SET 21 7357V	7 EA	X
3-18-160	WC4D	MICROCLAVE INJECTION CAP (B3300)	1 EA	O
3-54-219	WE3A	DRESSING CHANGE KIT (MSDC 009963)	1 EA	X

RETURNABLE EQUIPMENT AGREEMENT: I under[illegible]d that I have received this equipment in good condition. I will return the equipment in good co[illegible]n upon completion of therapy by contacting Chartwell Pennsylvania at 1-800-755-[illegible]

PICKED BY: STP CHECKED BY: STP / _____ PACKED BY: _____

4. When matching the medications with the delivery slip, mark your initials in the QTY delivered column. This is acknowledgement that the **correct drug** for the **correct patient** is in the delivery.
    a. For non-compounded medications, (i.e. MVI, hydration, IGG etc.), it also acknowledges that the NDC was double checked.
    b. For compounded medications, inspection that the CSP does not exhibit any defects such as precipitation, cloudiness, or leakage.
5. Initial in the appropriate sign off area.



MEDICATIONS

Rx #	Description	Qty Ord	Qty Deliv	Lot #	Exp Date
477133-0	LACTATED RINGERS 660 mL + Additives		STP		
444935-42	1-61-843 10ml 0.9% Sodium Chloride/12ml Syringe	20 @ 1 EA	X	H12xK7	4/12/15
444936-44	1-28-232 50 Units Heparin/5ml in 12ml syringe(10uni...	8 @ 1 EA	X	12345	4/12/15

SUPPLIES

Code	Bin	Description	Qty Ord	Qty Deliv
5-90-114		BATTERY DURACELL COPPERTOP ALKALINE 9V	3 EA	X
3-11-211	WC3A	CADD PRIZM HI VOLUME SET 21 7357V	7 EA	X
3-18-160	WC4D	MICROCLAVE INJECTION CAP (B3300)	1 EA	X
3-54-219	WE3A	DRESSING CHANGE KIT (MSDC 009963)	1 EA	X

RETURNABLE EQUIPMENT AGREEMENT: I understand that I have ed this equipment in good condition. I will return the equipment in good condition upon comp of therapy by contacting Chartwell Pennsylvania at 1-800-755-4704.

PICKED BY: STP CHECKED BY: STP / STP PACKED BY:

Employee packing the delivery (pharmacist or Dispatcher)

1. Copy 1
   a. Add the number of pieces in the appropriate spaces at the top of the packing slip.
   b. Initial in the "Packed By" area. This is an acknowledgement that the delivery was packed appropriately.

1 Bag 1 Cooler ___Box ___IV Pole ___Sharps

CHARTWELL PENNSYLVANIA 215 BEECHAM DRIVE SUITE #1 PITTSBURGH, PENNSYLVANIA 15205
(800)755-4704 (412)920-7500 WWW.CHARTWELLPA.COM

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

MEDICATIONS 1 BAG / 1 Cooler

Rx #	Description	Qty Ord	Qty Deliv	Lot #	Exp Date
477133-0	LACTATED RINGERS 660 mL + Additives	7	STP		
444935-42	1-61-843 10ml 0.9% Sodium Chloride/12ml Syringe	20 @ 1 EA	✓	A6XR7	4/20/19
444936-44	1-28-232 50 Units Heparin/5ml in 12ml syringe(10uni...	8 @ 1 EA	✓	12345	4/20/19

SUPPLIES

Code	Bin	Description	Qty Ord	Qty Deliv
5-90-114		BATTERY DURACELL COPPERTOP ALKALINE 9V	3 EA	✓
3-11-211	WC3A	CADD PRIZM HI VOLUME SET 21 7357V	7 EA	✓
3-18-160	WC4D	MICROCLAVE INJECTION CAP (B3300)	1 EA	✓
3-54-219	WE3A	DRESSING CHANGE KIT (MSDC 009963)	1 EA	✓

RETURNABLE EQUIPMENT AGREEMENT: I understand that I have received this equipment in g condition. I will return the equipment in good condition upon completion of therapy by contacting Chartwell Pennsylvania at 1-800-755-4704.

PICKED BY: STP CHECKED BY: STP / STP PACKED BY: STP

1. Copy 2
   a. Add the number of pieces in the appropriate spaces at the top of the delivery slip.
   b. Initial in the "Packed By" area

1 Bag 1 Cooler ___Box ___IV Pole ___Sharps

CHARTWELL PENNSYLVANIA 215 BEECHAM DRIVE SUITE #1 PITTSBURGH, PENNSYLVANIA 15205
(800)755-4704 (412)920-7500 WWW.CHARTWELLPA.COM

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

MEDICATIONS (1) BAG / (1) Cooler

Rx #	Description	Qty Ord	Qty Deliv	Lot #	Exp Date
477133-0	LACTATED RINGERS 660 mL + Additives	7			
444935-42	1-61-843 10ml 0.9% Sodium Chloride/12ml Syringe	20 @ 1 EA			
444936-44	1-28-232 50 Units Heparin/5ml in 12ml syringe(10uni...	8 @ 1 EA			

SUPPLIES

Code	Bin	Description	Qty Ord	Qty Deliv
5-90-114		BATTERY DURACELL COPPERTOP ALKALINE 9V	3 EA	
3-11-211	WC3A	CADD PRIZM HI VOLUME SET 21 7357V	7 EA	
3-18-160	WC4D	MICROCLAVE INJECTION CAP (B3300)	1 EA	
3-54-219	WE3A	DRESSING CHANGE KIT (MSDC 009963)	1 EA	

RETURNABLE EQUIPMENT AGREEMENT: I understand that I have received this equipment in gc condition. I will return the equipment in good condition upon completion of therapy by contacting Chartwell Pennsylvania at 1-800-755-4704.

PICKED BY:_____ CHECKED BY:_____/_____ PACKED BY: STP

Additional Pharmacist sign off's

Pump

1. Pharmacist
    a. Initial in the Exp. Return column which is an acknowledgement that the equipment is in the delivery and that the serial number was verified. i.e., Freedom pump, Enteral pump, Power Pack, and Solis Battery Pack (which will need to be removed from the pump to validate).
        i. The AC adaptors and pole clamps do not have specific serial numbers.
    b. CADD Prizm, CADD Solis, and Curlin pumps
        i. The first initial is an acknowledgement that the pump is in the delivery and that the serial number was verified, and the pump was programmed.
        ii. The second initial is the double-checking pharmacist.

EQUIPMENT

Code	Description	Serial #	Asset Tag	Exp. Return
5-81-500	POWER PACK	992536	CP02137	STP
5-81-500	POWER PACK	995607		STP
5-72-110	CADD PRIZM 6100	763820	CO2387	STP FB

Paperwork

1. Pharmacist
    a. Initial in the Qty deliver column. This is an acknowledgement that you added the paperwork to the delivery.

7-00-005	PATIENT WELCOME HANDBOOK	1 EA	STP
7-01-014	CADD-Prizm Power Pack Usage Instruction	1 EA	STP
5-66-118	CADD 3000ML PUMP BACKPACK	1 EA	X
7-01-010	Administration of TPN via CADD- Prizm Pump	1 EA	STP
7-00-009	NEW PHARMACY ORDERS	1 EA	STP
7-01-015	3 Liter Backpack teaching sheet	1 EA	STP

Packing list checking guide

1. Did you verify all three copies are for the same patient?
2. Is there an "✓" next to all supplies?
    a. If NO, you need to follow up!
3. Is there an initial next to all medications, equipment and paperwork?
4. Are there any circles?
    a. If so, something may be missing. Please address.
5. Did you check the last page?
    a. If NO, please do so. There may be an item hiding at the top of the page.
6. Equipment
    a. Did you verify the serial number of equipment is correct?
    b. Did you program CADD Prizm, CADD Solis or Curlin pump?
    c. Did you initial appropriately acknowledging that the serial number was validated, pumps were programmed as appropriate and the equipment it is in the delivery?
7. Did you initial the appropriate areas?
    a. Checking of supplies
    b. Combining of drug and supplies
    c. Packing of delivery
        i. Did you put the number of pieces in the appropriate area?
        ii. Did you initial and add the number of pieces to Copy 2?
8. If forwarding to dispatch for pack up,
    a. Did you find anything paper clipped to the packing slip?
        i. If so, follow up.
    b. Did you turn your mixing reports sideways to ensure that they do not go to the patient?
9. Check delivery ticket per protocol.
    a. Check that all initials and markings are present to verify that the delivery is ready to go.
    b. Remember to place your auxiliary stickers on the packing slip, when appropriate, both copies.

Review Date	Change Description/ Explanation	Effective Date	Education Date(s)	Name of reviewer
10-19-23				Stephanie Pancheri
10-30-24	No changes			Stephanie Pancheri
10-1-25	No changes			Stephanie Pancheri

CHARTWELL Pharmacy

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Standard Operating Procedure

Effective: October 2023

Title: Mixing Report Documentation

Objective: Provide accountability of tasks completed

Procedure:

Mixing Report Header

Mixing Report

Report Date: 01/06/2022 06:56PM EST

RX #:0-0

LOC:_____ ROUTE:_____ MIX/DELIVER:_____ DATE DUE:_____ TIME_____

- LOC: Location -- enter the hood that the medication was compounded in,
- Route –enter any specific delivery routes to help your technicians prioritize mixing (i.e., your Route #1 is targeted for 7-9am. Route 2 is 12-2pm. Obviously you want to mix route 1 before 2). This ties into Mix/Deliver.
- Mix/Deliver- indicate Mon/Tues, Tues/Tues, Wed/Thur, etc. This can help your pharmacy team work ahead and your technicians to properly file paperwork in the right day's work bin. Date due and time are there, helping further refine the work effort for the technician.
- Date Due – Date the medication is to be infused by the patient.
- Time Due – For same day deliveries, it is the time that the medication needs to be compounded by to meet the delivery expectations for the patient and nurse.

Mixing Report Footer

PICKED BY:_____ PREPARED BY:_____ TIME START/END:_____/_____ CHECKED BY:_____

ABACUS CHECK 1:_____ ABACUS CHECK 2:_____ CHEMO CHECK:_____

- Picked by – Individual who pulled the medications/supplies for compounded.
- Prepared by –Individual who prepared the medication.
- Time start/end –Enter start and end time of the compounding.
- Check by – Pharmacist who verified the CSP is as expected (e.g. free of inappropriate visible particulates or other foreign matter, discoloration, or other defects). The CSP and its labeling match the prescription/medication order. The container closure is free of defects (e.g. leakage, cracks in the container, or improper seals.
- Abacus check 1 – Pharmacist entering the order for the first time or entering the refill.
- Abacus check 2 –Pharmacist Double checking the new orders.
- (New Order: Abacus 1 and 2; Refill Order: Abacus 1)
- Chemo check – Pharmacist who checks the chemotherapy in the BSC prior to compounding.

Standard Operating Procedure

Effective: October 2023

Review Date	Change Description/ Explanation	Effective Date	Education Date(s)	Name of reviewer
10-2-24	No changes			Stephanie Pancheri
10-1-25	No Changes			Stephanie Pancheri

CHARTWELL Pharmacy

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Chartwell Pennsylvania, LP
1-800-755-4704
1001 Oakdale Road, Oakdale PA, 15071
www.chartwellpa.com

Sterile Compounding Questionnaire

Section 2: Sterile Compounding Questions

Question 15: Describe your initial and ongoing training program for all personnel performing sterile compounding:

- *See Attached Policies*
  - *PH 200 "Personnel Training and Education*
  - *Attachment Aseptic Technique in the non-hazardous room checklist*

CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

CHARTWELL Pharmacy

TITLE: PERSONNEL TRAINING AND EVALUATION	POLICY NUMBER: PH200
TJC STANDARDS: MC.02.01.07 EP 2, 3, 4; MC.02.01.09 EP 2, 3, 4, 5, 6, 7; MC.02.01.11 EP 3, 4, 5, 6; MC.03.01.01 EP 3; MC.03.06.07 EP 1; MC.04.02.03 EP 5	ACHC STANDARDS: DRX7-8N.01, DRX7-8O, DRX7-8O.01, DRX7-8P, DRX7-8Q, DRX7-8Z.02
EFFECTIVE DATE: 1/1/21	REVISION DATE: 9/1/21, 8/1/22, 11/1/23, 11/1/24, 1/2/25
REVIEW DATE: 5/1/21, 5/1/22, 8/1/22, 11/1/23, 11/1/24, 1/2/25	APPROVAL AUTHORITY: KATHLEEN PATRICK

I. POLICY

The designated person or assigned trainer is responsible for ensuring that all new employees who will compound sterile products undergo initial training and competency of core skills followed by validation testing of hand hygiene, garbing, and sterile technique, in both the non-hazardous and hazardous environments, prior to compounding any products for patient use. This validation testing represents the most challenging or stressful conditions encountered by the compounding staff. Frequency of training and competency assessment are outlined below.

II. PROCEDURES

A. Demonstrating Knowledge and Competency of Core Skills

1. Prior to independently preparing CSPs, compounding personnel must complete training and demonstrate knowledge in core skills to prove understanding in how to compound sterile preparations safely and effectively.

2. This training and competency (i.e. didactic training) must be completed initially and every 12 months. Note: This training is in addition to the validation testing noted below.

3. Training and competency must include but is not limited to the topics listed below:

   a. Hand Hygiene
   b. Garbing
   c. Cleaning and Disinfecting
   d. Aseptic Technique
   e. Achieving and/or maintaining sterility
   f. Use of Equipment
   g. Documentation of the Compounding Process
   h. Principles of High-Efficiency Particulate Air (HEPA)-filtered unidirectional airflow within the ISP Class 5 area

i. Proper use of PECs
j. Principles of movement of materials and personnel within the compounding area

B. Overview of Validation Testing

1. All new compounding personnel will be required, initially and every 6 months, to validate the effectiveness of their hand hygiene, garbing, and sterile technique, in both the hazardous and non-hazardous environments, prior to compounding products for patient use.

   a. The designated person may elect to validate technique on a more frequent basis.

2. Testing procedures to assess hand hygiene, garbing and aseptic techniques will be completed by the Designated Person or an assigned trainer using observation following the Hand Hygiene and Garbing Competency Assessment and by confirming negative results from the Gloved Fingertip Sampling procedure, whose guidance is set forth in the United States Pharmacopeia Chapter 797 (USP <797>).

3. Personnel that are only involved with in-process checks or final verifications of CSPs will be required to complete gloved fingertip testing (post garb assessment) and media fill testing annually with their other competency training.

4. Additional personnel not otherwise listed (i.e. not responsible for direct compounding) may be required to undergo additional competencies at the discretion of the DP and/or Pharmacy Director.

5. All results of testing will be documented by individual practice site SOPs.

C. Initial Validation

1. Demonstrating Competency in Garbing and Hand Hygiene

   a. Garbing and Hand Hygiene competency consists of both visual observation (following all procedures outlined in PH104 Attachment 4: Competency Assessment: Hand Hygiene and Garbing) and Glove and Fingertip Testing.
   b. The competency must be completed no fewer than 3 separate times

      i. The 3 successful completions must be in succession – failure to of any of the test require a repeat until 3 evaluations are completed in a row.
      ii. Each of the 3 initial competency evaluations must occur after a separate and complete hand hygiene and full garbing procedure.

   c. Glove Fingertip Sampling

i. Sampling procedures will follow those outlined in USP <797> Section 2.2.
ii. Negative results (no microbial growth) must be obtained from all 3 samples (each sample is one plate per hand) following an incubation period of at 30 °C - 35°C for 48 hours and then at 20°C-25°C for 5 additional days.
iii. Successful completion of the gloved finger-tip testing must be completed prior to beginning compounding CSPs or have a direct oversite of compounding personnel.
iv. Should failure of the competency occur, this should be documented and include the required details as outlined in USP<797>.

2. Demonstrating Testing in Aseptic Manipulation

a. Aseptic Manipulation evaluations consist of visual observation, media-fill, GFT of both hands and surface sampling of the direct compounding area.
b. Media Fill Testing

i. Testing procedures for assessing sterile technique will be accomplished using Media-Fill Challenge Test Kits based upon the most difficult compounded sterile product that the individual is to mix in both the hazardous and non-hazardous environments.
ii. If the personnel compounds only sterile to sterile products, then the media fill test can be conducted only utilizing sterile components.
iii. If the personnel compounds non-sterile to sterile products, then the media fill test must be conducted using non-sterile components.

c. Upon completion of the Media Fill Challenge Kit, the personnel must have their fingertips sampled from both hands INSIDE AN ISO CLASS 5 PEC.

i. Post Mixing Gloved Fingertips will be incubated as per all fingertip testing, but this test cannot have more than 3 CFUs on both plates combined.

d. Upon completion of the Media Fill Challenge Kit, the personnel's direct compounding area must be sampled (i.e. surface sampling)

i. Post mixing surface samples must not exceed 3 CFUs per plate. All other surface sampling procedures must be followed for post mixing surface sampling.

e. Media Fill Tests samples will be incubated at 20°C to 25°C or at 30°C to 35°C for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, the filled containers will be incubated for at least 7 days at each temperature. Failure is indicated by visible turbidity or other visual manifestations of growth in any sample on or before day 14.

f. A failure of any part of the media fill testing (Media Fill test kit growth, post mixing gloved fingertip and surface sampling exceeding CFU counts) will deem the entire aseptic manipulation competency as failed. Both demonstrations are required to be passed prior to compounding.

   i. Should failure of the competency occur, this should be documented and include the required details as outlined in USP <797>.

D. Ongoing Validation

1. Gloved Fingertip Testing (Post Garbing Assessment)

   a. Garbing and Hand Hygiene competency consists of both visual observation (following all procedures outlined in PH104 Attachment 1: Competency Assessment: Hand Hygiene and Garbing) and Glove and Fingertip Testing.
   Note: The competency only needs to be completed ONCE for ongoing validation.
   b. Negative results (no microbial growth) must be obtained from the sample (one plate per hand) following an incubation period of at 30°-35°C for 48 hours and then at 20°C-25°C for 5 additional days. If any of the sample tests positive (e.g., any CFUs are present), test must be repeated before being allowed to compound sterile preparations.

2. Media Fill Testing

   a. Ongoing validations will follow the same procedures as the Initial Validation Media Fill Test.

E. Media Fill Test Kits

1. Preferably, Media fill test kits will be based off commercially available kits that have a Certificate of Analysis associated with them.
2. Procedures for the media fill test will be developed by each individual practices site's designated person and placed into their SOPs.

F. Testing Plates

1. Plates (or paddles for gloved fingertip testing) must contain general microbial growth agar (e.g., trypticase soy agar [TSA]) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80)
2. Testing shall be completed per the manufacturer's specifications.

G. Personnel that conduct any validation testing must be training according to each site's SOPs

H. Should failure occur and/or serious gaps in aseptic technique be identified, the designated person will be notified to facilitate additional training/reorientation with further mitigation as appropriate.

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III. APPROVAL HISTORY

Approval Authority	Title	Date
Kathleen Patrick	President	01/01/2021
Kathleen Patrick	President	05/01/2021
Kathleen Patrick	President	09/01/2021
Kathleen Patrick	President	05/01/2022
Kathleen Patrick	President	08/01/2022
Kathleen Patrick	President	11/01/2023
Kathleen Patrick	President	11/01/2024
Kathleen Patrick	President	01/02/2025

Aseptic Technique in the Hazardous Room Checklist

This competency focuses on a demonstration of knowledge and behaviors that reduce the risk of contamination throughout common activities during the aseptic compounding process while working in the hazardous environment. It also focuses on a demonstration of knowledge and behaviors that ensure proper personnel hygiene habits, hand washing and garbing as well as use of personal protective equipment (PPE).

Competencies:	Satisfactory (✓/X)
Exits the main compounding room and enters the Hazardous Ante Room.	
Is aware of the line of demarcation separating clean and hazardous sides and observes required activities.	
Dons a second pair of shoe covers or a pair of shoe covers over designated clean area shoes one at a time, placing the covered shoe on the hazardous side of the line of demarcation, as appropriate.	
Dons a second gown (chemo) by selecting the appropriate size and examining for any holes, tears, or other defects and ensure full closure.	
Dons a second appropriate size sterile (chemo) gloves ensuring that there is a tight fit with no excess glove material at the finger tips with no defects, holes, or tears.	
Routinely disinfects gloves and items with 70% sterile alcohol prior to working in the direct compounding area and after touching items or surfaces that may contaminate gloves.	
Works 6 inches in the hood, placing only arms and hands in the work area.	
Ensures syringes, needles and tubing remain in their individual packaging and are opened in ISO Class 5 work area.	
Disinfects all points of entry every time and allows sufficient time to dry.	
Does not block inlet grid with supplies and debris (BSC cabinet only). When entering vials and bags ensure needle is on a 45 degree angle with bevel up.	
Uses scooping method when recapping needle is necessary.	
Cleans spills between orders.	
Does not block air flow with hands when manipulating vials or adding to bag.	
Avoids touching critical areas of syringe (needle, hub, barrel).	
Labels products outside of the hood/Labels products correctly.	
Disposes of sharps and waste according to institutional policy or recognized guidelines.	
Removes chemo gown and chemo gloves on the hazardous side of the Hazardous Ante Room.	
Removes shoe covers one at a time, ensuring that uncovered foot is placed on the clean side of the line of demarcation.	
Removes gown and discards it.	
Removes gloves and performs hand hygiene.	
Exits the Hazardous Ante Room into the Ante Room.	
Removes and discards mask, head cover, and beard cover, if used.	
Removes shoe covers one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation. Removes and discards shoe covers every time the compounding area is exited.	

Revised 11/2019

Aseptic Technique in the Hazardous Room Checklist (cont.)

Person Being Tested: _____
Facility: _____
Observed On: _____
Observed By: _____
Notes:

***The examinee should be immediately informed of all unacceptable practices and informed of and demonstrated correct practices.

Aseptic Technique in the Non-Hazardous Room Checklist

This competency focuses on a demonstration of knowledge and behaviors that reduce the risk of contamination throughout common activities during the aseptic compounding process while working in the non-hazardous environment. It also focuses on a demonstration of knowledge and behaviors that ensure proper personnel hygiene habits, hand washing and garbing as well as use of personal protective equipment (PPE).

Competencies:	Satisfactory (✓/X)
Presents in a clean and appropriate attire and manner.	
Removes all jewelry, make-up, and personal electronic devices.	
Does not store or bring food or drinks in the ante-areas or buffer areas.	
Is aware of the line of demarcation separating clean and dirty sides and observes required activities.	
Dons shoe covers or designated clean area shoes one at a time, placing the covered or designated shoe on clean side of line demarcation, as appropriate.	
Dons head cover.	
Dons beard cover if necessary.	
Dons face mask to cover bridge of nose down to include chin.	
Uses nail pick and soap to clean under nails under warm running water.	
Washes hands and forearms with soap and water using an adequate amount of soap to allow thorough hand washing for at least 30 seconds and then dries hands and forearms using low linting wipes.	
Dons gowns by selecting the appropriate size and examining for any holes, tears, or other defects and ensure full closure.	
Opens sterile gloves.	
Disinfects hands again using a waterless alcohol-based surgical hand scrub and allows hands to dry thoroughly before donning sterile gloves.	
Dons appropriate size sterile gloves ensuring that there is a tight fit with no excess glove material at the finger tips with no defects, holes, or tears.	
Completes Gloved Fingertip Sampling without sanitizing gloves prior and then discards gloves.	
Disinfects hands again using a waterless alcohol-based surgical hand scrub and allows hands to dry thoroughly before donning sterile gloves.	
Dons appropriate size sterile gloves ensuring that there is a tight fit with no excess glove material at the finger tips with no defects, holes, or tears.	
Sanitizes gloved hands with 70% sterile IPA prior to entering the PEC.	
Cleans the PEC following the proper sequence.	
Routinely disinfects gloves and items with 70% sterile alcohol prior to working in the direct compounding area and after touching items or surfaces that may contaminate gloves.	
Works 6 inches in the hood, placing only arms and hands in the work area.	
Cleans, sets up, and calibrates automated compounding device according to manufacturer's instructions.	

Aseptic Technique in the Non-Hazardous Room Checklist (cont.)

Competencies:	Satisfactory (✓/X)
Ensures syringes, needles and tubing remain in their individual packaging and are opened in ISO Class 5 work area.	
Disinfects all points of entry every time and allows sufficient time to dry.	
Does not block inlet grid with supplies and debris (BSC cabinet only).	
When entering vials and bags, ensures needle is on a 45 degree angle with bevel up.	
Uses scooping method when recapping needle is necessary.	
Cleans spills between orders.	
Does not block air flow with hands when manipulating vials or adding to bag.	
Breaks ampules towards the side of the hood while wrapping an alcohol wipe around the top of the ampule to avoid injury and filters the solution when withdrawing from the ampule.	
Avoids touching critical sites (needle, hub and plunger of syringe, vial stopper, etc.) when compounding.	
Labels products outside of the hood/Labels products correctly.	
Disposes of sharps and waste according to institutional policy or recognized guidelines.	
Removes and discards gloves, gown, mask, head cover and beard cover, if used.	
Removes shoe covers one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation. Removes and discards shoe covers every time the compounding area is exited.	
Person Being Tested: _____	
Facility: _____	
Observed On: _____	
Observed By: _____	
Notes:	

***The examinee should be immediately informed of all unacceptable practices and informed of and demonstrated correct practices.

CHARTWELL Pharmacy

Chartwell Pennsylvania, LP
1-800-755-4704
1001 Oakdale Road, Oakdale PA, 15071
www.chartwellpa.com

Sterile Compounding Questionnaire

Section 2: Sterile Compounding Questions

Question 16: Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

- *See attached policies*
  - *PH110 "Cleaning and Disinfecting of the Compounding Area"*
  - *SOP: Chartwell Pennsylvania, LP Oakdale Infusion Pharmacy Cleaning SOP*
  - *Attachment 3: Competency Assessment: Cleaning and Disinfection Procedures*

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TITLE: CLEANING AND DISINFECTING OF THE COMPOUNDING AREA	POLICY NUMBER: PH110
URAC STANDARDS: N/A	ACHC STANDARDS: DRX4-7C, DRX4-14F, , DRX7-8F, DRX7-8G, DRX7-8N.01, DRX7-8P, DRX7-8Z.12, DRX7-12A,
TJC STANDARDS: N/A	
EFFECTIVE DATE: 1/1/21	REVISION DATE: 9/1/21, 8/1/22, 10/1/23, 4/15/24, 1/2/25, 5/1/25
REVIEW DATE: 5/1/21, 5/1/22, 8/1/22, 10/1/23, 4/15/24, 1/2/25, 5/1/25	APPROVAL AUTHORITY: KATHLEEN PATRICK

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Attachment #3: Competency Assessment: Cleaning and Disinfection Procedures....Error! Bookmark not defined.

IV. APPROVAL HISTORY....9

I. POLICY

To describe, standardize and define the process by which the controlled environments (ISO Class 5, 7, and 8) and the general pharmacy preparation area are cleaned, disinfected, and maintained in a manner that ensures an environment suitable for compounding sterile preparations. Environmental contact is a major source of microbial contamination of CSPs, therefore scrupulous attention to cleaning and disinfecting of the areas used for sterile compounding is required to reduce and minimize this potential source of CSP contamination.

II. PROCEDURES

A. Policies

1. Since surfaces in ISO Class 5 Primary Engineering Controlled (PEC) work areas, including Laminar Air Flow Workbenches/Hoods (LAFWs) and Biological SAFETY Cabinets (BSCs) are most intimate

to the exposure of critical site, they require disinfecting most frequently. These areas must be cleaned and disinfected (or deactivated & decontaminated) on a regular basis, including but not limited to:

a. The beginning of each compounding shift
b. Immediately prior to each batch
c. Every 30 minutes throughout the compounding shift when ongoing compounding activities are occurring.
d. After spills
e. When microbial contamination is known to have been or is suspected of having been introduced
f. After certification, preventative maintenance, or repairs to equipment/room structure

2. Manufactured designated STERILE products ONLY are allowed for cleaning and disinfecting the PEC.

3. Though the general pharmacy preparation area is not an ISO "classified" environment, it must be kept clean and orderly.

4. No high particle shedding materials may enter the buffer area/cleanroom. This includes corrugated cardboard, paper documents (i.e. compounding worksheets and order forms are allowed but should be kept to a minimum). No worksheets or order forms may enter the ISO Class 5 environment compounding surface at any time. Mixing reports will be placed in a zip lock bag upon entry of ISO Class 5 room and removed minimally as needed.

5. Ideally, disinfection of the general compounding area (buffer area/cleanroom and anteroom/area) shall occur at the end of the compounding shift.

6. If cleaning must occur at the start of the compounding day, all cleaned surfaces must be dry PRIOR to starting any compounding activity.

7. If any compounding occurs during after-hours conditions (on-call situation), additional cleaning may occur at the start of the next business day.

8. Cleaning and disinfection of the controlled environments will not be performed while compounding is taking place.

9. Pharmacy compounding personnel must ensure that cleaning is being performed properly and by personnel who have been adequately trained on the policy and procedures, as well as on hand hygiene and garbing.

10. Due to unique environments in each pharmacy branch, site specific daily and monthly cleaning SOPs are maintained by each specific pharmacy Designated Person. See PH110 Attachment 1: Infusion Pharmacy Cleaning Standard Operating Procedures (Chartwell- Oakdale) and PH110 Attachment 2: Infusion Pharmacy Cleaning Standard Operating Procedures (Chartwell- Altoona), respectively.

11. Cleaning is performed from the top down, in this order:

a. Ceilings
b. Walls
c. Counters, sinks, and easily cleanable work surfaces including stools, carts, shelves, etc.
d. Phones and other devices
e. Outside then Inside surfaces of ISO Class 5 PECs
f. Floors

12. Cleaning Equipment and Supplies:
    a. Shall be stored in a designated area to ensure segregation from compounding supplies
    b. Materials used must be non-shedding and preferably composed of synthetic microfibers.
    c. Materials used must be dedicated to use in specific areas (buffer area/cleanroom, ante-area/room, segregated compounding area, etc.) and will not be moved from these areas except for disposal.
    d. Microcinch or KleanMax Mop is used to maintain the floors. There are mop pads designated for use in the negative pressure room, antibiotic room, TPN room, and the anteroom.
    e. For any reusable cleaning equipment:
        1) Used or saturated mop heads should be thrown away
        2) Manufacturer's instructions on the product used to ensure the effectiveness of the device is maintained and that repeated use does not add to the bioburden of the areas cleaned.
13. Since disinfectant solutions are irritants and can damage the skin and eyes, safety glasses (provided by the pharmacy) should be worn during cleaning of ceilings and walls when there is an increased likelihood of splashing or dripping of solution.

14. Safety Data Sheets (SDS) must be readily available for reference for all decontaminants, cleaners and disinfectants used in the decontamination, disinfection, and cleaning process.
    a. Available at msds.com

15. Tacky Mats:
    a. May be placed at the entrance to controlled areas within the pharmacy compounding area to remove debris from personnel and equipment as they enter these areas.
    b. The Managing Pharmacist, or designee, will determine the location of the tacky mats depending on workflow and room configuration.
    c. Tacky mats must be changed at least daily or more frequently if needed.
    d. Tacky mats will NOT be placed in any ISO area.

16. Any compounding equipment (automated compounders, devices, or pumps) placed into ISO Class 5 PECs are subject to the same cleaning requirements as the LAFW or BSC, itself.

17. If any equipment or device used to compound sterile preparations is removed from the ISO Class 5 buffer area/cleanroom, it must be properly cleaned and disinfected prior to being placed back into service within that environment.

B. Materials and Equipment: *Items listed are examples of industry approved products.

1. Single use sterile cleaning pads

a. Microcinch Mop (clean pads), Kleanmax mop (clean pads)
b. Easy reach tool with Quiltec Sterile pads

2. Sterile Disinfecting Agent
   a. TB1-3300 (dwell time of 1 minute)

3. Disinfecting Agent
   a. PREempt-Plus RTU (dwell time of 1 minute)

4. Sterile Sporicidal Agent
   a. Sterile Peridox RTU (dwell time of 3 minutes on step #1 ONLY)

5. Sporicidal Agent
   a. Peridox RTU

6. 70% sterile IPA
   a. Prostate Sterile IPA wipes

7. Low particle shed wipes if applicable

C. Daily Cleaning of the non-HD PEC (i.e. Laminar Air Flow Workbench)

1. Gown and glove, in accordance with Hand Hygiene and Garbing Procedure

2. If the LAFW has been turned off, restart and allow to run a minimum of thirty (30) minutes prior to cleaning. Ideally, PECs should never be turned off.

3. Apply sterile disinfecting agent to low-lint wipe or pad of Easy Reach Tool.

4. Using unilateral overlapping strokes, clean all surfaces of the hood from top to bottom and back to front.
   a. **NOTE:** Do not wipe in a large circular motion across the work surface, as it is likely that contaminants and particulate matter will be introduced into the rear portion of the hood as they are captured, carried, and deposited from the front edge of the LAFW.

5. Allow a dwell time of **ONE** minute.

6. Using a second wipe or pad, repeat step 4 with Sterile 70% IPA
   a. **NOTE:** Do not splash or spray the HEPA filter with disinfectant solution. Carefully clean the HEPA grills.

7. Allow all surfaces to dry before compounding begins.

8. If the daily cleaning was performed the night before, at the start of each new workday, the LAFW must be wiped down with a wipe wetted with sterile 70% IPA.

9. During the compounding process, sterile 70% IPA must be applied to the horizontal work surface, including any removable work trays of the PEC at least every 30 min if the compounding

process takes 30 min or less. If the compounding process takes more than 30 min, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding.

10. Prior to, and after performing any compounding in the horizontal laminar flow hood, the cabinet will be visually inspected for gross contamination. If gross contamination is identified at any point, the cabinet will be completely cleaned according to the approved methods outlined herein, based on suspected contaminant and escalated to pharmacy leadership for further investigation. Interventions will be documented using PH202 Attachment 1: Environmental Monitoring Investigation & Correction Action Plan.

11. Once monthly, utilize and apply Peridox RTU follow steps 3-7 above. Ensure additional dwell time of 3 minutes is applied for Sterile Peridox.

12. Document all cleaning activities on file.

D. Daily Cleaning of the HD BSC (Biologic Safety Cabinet)

1. Gown and glove, in accordance with Pharmacy Policy: Aseptic Compounding Considerations when compounding hazardous drugs.

2. If the BSC has been turned off, restart and allow to run a minimum of thirty (30) minutes prior to cleaning. Ideally, PECs should never be turned off.

3. Apply Sterile Peridox RTU to low-lint wipe or pad of Easy Reach Tool.
   a. Agents used for deactivation, decontamination and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue.

4. Using unilateral overlapping strokes, clean all surfaces of the hood from top to bottom and back to front.
   a. **NOTE:** Do not wipe in a large circular motion across the work surface, as it is likely that contaminants and particulate matter will be introduced into the rear portion of the hood as they are captured, carried, and deposited from the front edge of the BSC.

5. Allow a dwell time of **THREE** minutes after the first application.

6. Repeat steps 3-4 with a second application of Peridox RTU.

7. Using a second wipe or pad, repeat step 4 with Sterile 70% IPA
   a. **NOTE:** Do not splash or spray the HEPA filter with disinfectant solution. Carefully clean the HEPA grills.

8. Allow all surfaces to dry before compounding begins.

9. Place all soiled wipes, covers and cleaning supplies into a disposable bag and place in Yellow Trace Chemo bin.

10. If the daily cleaning was performed the night before, at the start of each new workday, the LAFW must be wiped down with a wipe wetted with sterile 70% IPA.

11. During the compounding process sterile 70% IPA must be applied to the horizontal work surface, including any removable work trays of the PEC at least every 30 min if the compounding process takes 30 min or less. If the compounding process takes more than 30 min, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding.

12. Prior to, and after performing any compounding in the biological safety cabinet, the cabinet will be visually inspected for gross contamination. If gross contamination is identified at any point, the cabinet will be completely cleaned according to the approved methods outlined herein, based on suspected contaminant and escalated to pharmacy leadership for further investigation. Interventions will be documented using PH202 Attachment 1: Environmental Monitoring Investigation & Correction Action Plan.

13. Once monthly the front of the BSC must be lifted to thoroughly decontaminate, clean and disinfect, including underneath the deck.
    a. Don the PAPR, for optimal respiratory protection, in addition to all other required PPE when cleaning the BSC.

14. Document all cleaning activities on file.

E. Daily Cleaning of Controlled Environments (i.e. Buffer room) with Preempt-Plus RTU (Peridox RTU for Negative Pressure Controlled Environments)

1. Cleaning must occur from the cleanest to the dirtiest areas. The lowest ISO Class room or environment (ISO Class 5) must be cleaned before the ISO Class 7 buffer area/cleanroom followed by the ISO Class 7/8 ante-area then general pharmacy preparation area.
    a. An exception to this rule is when each room has its own dedicated cleaning supplies.

2. Each compounding day the following must be cleaned in both the buffer area/cleanroom and in the ante-area/room.
    a. The inside surfaces of all ISO Class 5 PECs
    b. Other counters and easily cleanable work surfaces (ie. stool tops, metro cart, shelves, etc.)
    c. Phones and other devices
    d. Pass-through and door handles
    e. All surfaces of moveable carts
    f. Floors

3. Daily Cleaning the Floors in the Compounding Room
    a. Apply Preempt-Plus RTU to mop head of Microcinch or Kleanmax Mopping System.
    b. Mop hard to reach area first, then remainder of floor in an 'S' motion as you exit the room.
    c. Allow Preempt to stay wet for 1 minute.
    d. Change the mop head, during the floor clean, if it is visibly soiled >15%.
    e. Preempt may leave a residue after a few days, due to the detergent. If so, wipe the floors when necessary with sterile or distilled water after the cleaning is done.

f. Follow same protocol for negative pressure room except for using Peridox RTU in place of Preempt-Plus RTU. Dwell time is 3 minutes for Peridox RTU.
g. When mopping in Chemo room is completed, dispose of used products in sealed bag and dispose into the Yellow Trace Chemo container.

4. The SEC will be visually inspected for gross contamination. If gross contamination is identified at any point, the affected location will be completely cleaned according to the approved methods outlined herein, based on suspected contaminant and escalated to pharmacy leadership for further investigation. Interventions will be documented using PH202 Attachment 1: Environmental Monitoring Investigation & Correction Action Plan.

5. Document the cleaning on file.

F. Monthly Cleaning of the Ceilings, Walls, and Floors with Peridox RTU

1. Before starting, protective eyewear should be donned as well as charcoal N95 respirator in addition to normal PPE for respective areas.

2. Apply Peridox to Mop Head of Microcinch or Kleanmax Mopping System.

3. Saturate mop head to full saturation but not dripping wet.

4. Begin at the furthest location from the door for all these surfaces.

5. Use unilateral overlapping strokes.

6. For walls, clean from top to bottom. Stop approximately 1 foot from floor. Clean this area of the wall last using horizontal strokes.

7. Clean floors, starting with hard-to-reach surfaces then work your way out of the room.

8. Change the microfiber wipe if it looks visibly soiled >15%.

9. Dispose of the Microfiber pad in a sealed zip lock bag to contain contamination and odor. When cleaning the chemo room, dispose of used products in sealed bag and dispose into the Yellow Trace Chemo container.

10. **NOTE:** All surfaces cleaned daily with Preempt-Plus RTU must be cleaned monthly with Peridox RTU.

11. Document the cleaning on file.

G. Monthly Cleaning of Controlled Environments (ISO 7 and ISO 8 spaces)

1. Monthly cleaning includes all the elements of the daily cleaning plus the following must be cleaned during a monthly cleaning with Peridox RTU:
   a. Storage and shelving

b. All storage bins must have contents removed; bins cleaned inside and out, allowed to dry and contents replaced

2. Document the cleaning on file.

H. Routine Cleaning of the General Pharmacy Preparation Area

1. Though the general pharmacy preparation area is not an ISO "classified" environment, it must be kept clean and orderly.

2. Weekly cleaning of bins and monthly cleaning of pharmacy itself is performed.

3. Document cleaning on file.

I. Three-Time Cleaning of Controlled Environments

1. Although not defined in USP, Three-Time Clean (Triple Clean) consists of standard cleaning processes but with three rounds of cleaning. The first round consists of a sporicidal agent (Peridox) with a dwell time of 3 minutes. The second round consists of the sporicidal agent again. The final round involves 70% sIPA.

2. Three-time cleaning may be performed when the following conditions occur:
   a. After action levels are exceeded according to USP<797> – occurring during environmental monitoring air or surface sampling procedures.
   b. After any maintenance work performed in the cleanroom that could compromise environmental integrity. Scope of work performed to be evaluated by local leadership for final determination of level of cleaning required.
   c. If construction is conducted in an adjacent area to the controlled environments, communication will be shared with all employees.
      i. Should there be concern for environmental compromise, compounding will cease within the affected area and pharmacy leadership will be notified for further investigation. Interventions will be documented using PH202 Attachment 1: Environmental Monitoring Investigation & Correction Action Plan.

J. Floor Refinishing

1. The floors of the buffer area/cleanroom and ante-are shall be stripped of the existing finish (depending on floor type) and refinished by qualified personnel on an as needed basis.

2. The managing Pharmacist, or designee, will determine when this must occur.

3. The materials utilized will be of such composition as to not compromise the integrity of the controlled environment and should be manufactured for the expressed purpose of maintenance of the type of flooring which has been installed.

K. Ancillary Support Services

1. Any ancillary cleaning staff, who perform cleaning and disinfecting of the clean room, are trained in proper hand hygiene, garbing, cleaning, and disinfecting procedures as described in USP <797>. This training is conducted by the compounding supervisor, other qualified staff, or, if the organization chooses, a qualified compounding consultant.

2. A competency assessment of hand hygiene, garbing, cleaning, and disinfecting procedures will be conducted for all ancillary cleaning staff, at a minimum, when newly assigned and when procedures change.

III. APPROVAL HISTORY

Approval Authority	Title	Date
Kathleen Patrick	President	01/01/2021
Kathleen Patrick	President	05/01/2021
Kathleen Patrick	President	09/01/2021
Kathleen Patrick	President	05/01/2022
Kathleen Patrick	President	08/01/2022
Kathleen Patrick	President	10/01/2023
Kathleen Patrick	President	04/15/2024
Kathleen Patrick	President	01/02/2025
Kathleen Patrick	President	05/01/2025

Altoona, Pharmacist in Charge	Date 05/28/2025
Altoona, Hazardous Drug Designated Person	Date 05/28/2025
Altoona, USP Designated Person	Date 05/27/2025
Erie, Pharmacist in Charge	Date 05/27/2025
Erie, Hazardous Drug Designated Person	Date
Erie, USP Designated Person	Date 05/27/2025
Oakdale, Pharmacist in Charge	Date 05/27/2025

Marissa Davis (May 27, 2025 11:26 EDT)

05/27/2025

Oakdale, Hazardous Drug Designated Person — Date

Jessica Norris (May 27, 2025 10:46 EDT)

05/27/2025

Oakdale, USP Designated Person — Date

1. Any ancillary cleaning staff, who perform cleaning and disinfecting of the clean room, are trained in proper hand hygiene, garbing, cleaning, and disinfecting procedures as described in USP <797>. This training is conducted by the compounding supervisor, other qualified staff, or, if the organization chooses, a qualified compounding consultant.

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Kathleen Patrick	President	04/15/2024
Kathleen Patrick	President	01/02/2025
Kathleen Patrick	President	05/01/2025

Altoona, Pharmacist in Charge	Date 05/28/2025
Altoona, Hazardous Drug Designated Person	Date 05/28/2025
Altoona, USP Designated Person	Date 05/27/2025
Erie, Pharmacist in Charge	Date 05/27/2025
Erie, Hazardous Drug Designated Person	Date 5/28/2025
Erie, USP Designated Person	Date 05/27/2025
Oakdale, Pharmacist in Charge	Date 05/27/2025

CHARTWELL PENNSYLVANIA, LP

OAKDALE INFUSION PHARMACY CLEANING SOP

STANDARD OPERATING PROCEDURE

APPROVAL DATE: 08.01.2022/ EFFECTIVE DATE: 08.01.2022

OAKDALE PHARMACY OPERATIONS/ JESS NORRIS, MARISSA DAVIS, ALEX AMEREDES

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Objective

To describe, standardize and define the process by which the controlled environments (ISO Class 5, 7, and 8) and the general pharmacy preparation area are cleaned, disinfected, and maintained in a manner that ensures an environment suitable for compounding sterile preparations. Environmental contact is a major source of microbial contamination of CSPs, therefore scrupulous attention to cleaning and disinfecting of

the areas used for sterile compounding is required to reduce and minimize this potential source of CSP contamination.

General disclaimer: the following procedures are intended to be completed in addition to current policies and procedures, as well as established workflow for respective tasks.

1. TPN ROOM DAILY CLEANING PROCEDURES

Opening Procedures

1. Clean the ACDs and PECs with ***sterile TB1-3300***, utilizing the EasyReach® tool, followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)
2. Clean the carts with ***PREempt***
3. Clean the TPN pass through with ***PREempt***
4. Clean the door threshold areas with ***PREempt***
5. Clean the vents with ***PREempt***
6. Clean all high touch surfaces with ***PREempt*** (i.e. door handles, chair seats, backs, and adjustment knobs, clipboards, and garbage cans, etc.)
7. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***PREempt***) on the mop working your way towards the Ante Room, using an "s" or "pull/grab" method.

Closing Procedures

1. Tear down TPN machines not utilized by night shift (except on Friday/Saturdays)
2. Remove all expired fluids/open vials and dispose of appropriately
3. Ensure all hanging fluids/open vials left are in date/time and have visible times marked
4. Disinfect the ACDs and PECs with ***sterile 70% IPA,*** utilizing the EasyReach® tool (top to bottom, back to front, using overlapping strokes)
5. Wipe down carts, door handles, and TPN pass through with ***sterile 70% IPA***
6. Replace sharps containers as necessary
7. Place all miscellaneous daily use items back into the appropriate bin
8. Pick up visible trash from floor
9. Remove trash and place new double bags in each trash receptacle
10. Take out the trash

2. TPN ROOM MONTHLY CLEANING

1. Clean the ceilings, walls, and floors with ***Peridox***
2. Clean the vents with ***Peridox***
3. Clean the storage/shelving racks and storage bins with ***Peridox***
4. Clean the carts with ***Peridox***
5. Clean all high touch surfaces (i.e. door handles, chair seats, backs, and adjustment knobs, clipboards, and garbage cans, etc.) with ***Peridox***
6. Clean the outside of hoods with ***Peridox*** as well as wheels of hoods and cords
7. Clean the ACDs and PECs with ***sterile Peridox***, utilizing the EasyReach® tool, followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)

Procedure: Ceiling

1. Begin at the farthest corner of the room using ***Peridox***
2. Clean all irregular surfaces first
3. Mop with overlapping strokes *Replace Microcinch® mop head as needed*

Procedure: Walls

1. Mop utilizing ***Peridox,*** with overlapping strokes, down to antimicrobial wall ledge
2. Wipe ledge
3. Mop antimicrobial wall, with overlapping strokes, down to "baseboard" ledge
4. Finish mopping the wall, with the last foot of wall space not mopped, with horizontal strokes before beginning the floor

Procedure: Floor

1. The same mop **CANNOT** be used for the ceilings/walls can be used on the floor
2. Start at the cleanest part of the room using an "s" or "pull/grab" method, working your way towards the ante room

3. ANTIBIOTIC ROOM DAILY CLEANING PROCEDURES

Opening Procedures

1. Clean the ACDs and PECs with ***sterile TB1-3300***, utilizing the EasyReach® tool, followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)
2. Clean the carts with ***PREempt***
3. Clean the door threshold areas with ***PREempt***
4. Clean the pass through with ***PREempt***
5. Clean the vents with ***PREempt***
6. Clean all high touch surfaces with ***PREempt*** (i.e. door handles, chair seats, backs, and adjustment knobs, clipboards, and garbage cans, etc.)
7. Clean the robots with ***sterile TB1-3300***, utilizing the EasyReach® tool, followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)
8. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***PREempt***) on the mop working your way towards the TPN Room door, using an "s" or "pull/grab" method

Closing Procedures

1. Disinfect the ACDs and PECs with ***sterile 70% IPA,*** utilizing the EasyReach® tool (top to bottom, back to front, using overlapping strokes)
2. Clean the carts with ***sterile 70% IPA***
3. Clean the door handles and pass through with ***sterile 70% IPA***
4. Replace sharps containers as necessary
5. Place all miscellaneous daily use items back into the appropriate bin
6. Pick up visible trash from floor
7. Remove trash and place a new bag in each trash receptacle
8. Take out the trash

4. ANTBIOTIC ROOM MONTHLY CLEANING

1. Clean the ceilings, walls, and floors with ***Peridox***
2. Clean the vents with ***Peridox***
3. Clean the storage/shelving racks and storage bins with ***Peridox***
4. Clean the carts with ***Peridox***

5. Clean all high touch surfaces (i.e. door handles, chair seats, backs, and adjustment knobs, clipboards, and garbage cans, etc.) with ***Peridox***
6. Clean the outside of hoods with ***Peridox*** as well as wheels of hoods and cords
7. Clean the PECs with ***sterile Peridox***, utilizing the EasyReach® tool, followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)
8. Clean the robots with ***sterile Peridox***, utilizing the EasyReach® tool, followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)

Procedure: Ceiling

1. Begin at the farthest corner of the room using ***Peridox***
2. Clean all irregular surfaces first
3. Mop with overlapping strokes *Replace Microcinch® mop head as needed*

Procedure: Walls

1. Mop utilizing ***Peridox*** with overlapping strokes down to antimicrobial wall ledge
2. Wipe ledge
3. Mop antimicrobial wall with overlapping strokes down to "baseboard" ledge
4. Finish mopping the wall, with the last foot of wall space not mopped, with horizontal strokes before beginning the floor

Procedure: Floor

1. The same mop **CANNOT** be used for the ceilings/walls can be used on the floor
2. Start at the cleanest part of the room using an "s" or "pull/grab" method, working your way towards the TPN room

5. CHEMO ROOM DAILY CLEANING PROCEDURES

Opening Procedures

1. Don appropriate PPE (**2 gowns (outer gown must be poly coated), 2 pairs of gloves (outer glove must be ASTM certified for use with chemo drugs), 2 pairs of booties, and 1 mask while cleaning (N95 respirator mask if needed) as well**
2. Clean the ACDs and PECs with ***sterile Peridox (X2),*** *(allow a three-minute dwell time from the start of the second application of Peridox),* followed by disinfecting with ***sterile 70% IPA (X1), using a new cleaning pad,*** (top to bottom, back to front, using overlapping strokes, utilizing the EasyReach® tool)
3. Clean the carts with ***Peridox***
4. Clean the pass through with ***Peridox***
5. Clean the door threshold areas with ***Peridox***
6. Clean the vents with ***Peridox***
7. Clean all high touch surfaces with ***Peridox*** (i.e. door handles, chair seats, backs, and adjustment knobs, garbage cans, etc.)

8. Mop floor using Chemo Rooms mop with ***Peridox,*** starting with the cleanest area (Compounding Storage room first), using an "s" or "pull/grab" method, and ending at the door to the Sterile Ante Room
9. Double bag all the cleaning supplies and throw away in the RCRA bin

Closing Procedures

1. Don appropriate PPE (**2 gowns (outer gown must be poly coated), 2 pairs of gloves (outer glove must be ASTM certified for use with chemo drugs), 2 pairs of booties, and 1 mask while cleaning (N95 respirator mask if needed) as well**
2. Clean the ACDs and PECs with ***sterile Peridox (X2),*** *(allow a three-minute dwell time from the start of the second application of Peridox),* followed by disinfecting with ***sterile 70% IPA (X1), using a new cleaning pad,*** (top to bottom, back to front, using overlapping strokes, utilizing the EasyReach® tool)
3. Clean tops of carts with ***Peridox***
4. Double bag all the cleaning supplies and throw away in the RCRA bin
5. Pick up visible trash from floor
6. Enter sterile ante room and remove blue gloves, blue gown and second pair of booties while stepping over the line of demarcation and place in yellow chemo trash container
7. Take out trash and yellow sharps containers & RCRA bins (if full) being sure to secure lids on yellow sharps containers & RCRA bins

Check the incubator before you leave the room

6.CHEMO ROOM MONTHLY CLEANING

1. Clean the ceilings, walls, and floors starting with the cleanest area (Compounding Storage room first), with ***Peridox***
2. Clean the vents with ***Peridox***
3. Clean the storage/shelving racks and storage bins with ***Peridox,*** including the Compounding Storage room
4. Clean the outside of hoods with ***Peridox*** as well as wheels of hoods and cords
5. Clean the ACDs and PECs with ***sterile Peridox (X2),*** *(allow a three-minute dwell time from the start of the second application of Peridox),* followed by disinfecting with ***sterile 70% IPA (X1), using a new cleaning pad,*** (top to bottom, back to front, using overlapping strokes, utilizing the EasyReach® tool)
6. Double bag all the cleaning supplies and throw away in the RCRA bin

Procedure: Ceiling

1. Begin at the farthest corner of the room using ***Peridox***
2. Clean all irregular surfaces first
3. Mop with overlapping strokes *Replace Microcinch® mop head as needed*

Procedure: Wall

1. Mop utilizing ***Peridox*** with overlapping strokes down to antimicrobial wall ledge
2. Wipe ledge
3. Mop antimicrobial wall with overlapping strokes down to "baseboard" ledge

4. Finish mopping the wall, with the last foot of wall space not mopped, with horizontal strokes before beginning the floor

Procedure: Floor

1. The same mop **CANNOT** be used for the ceilings/walls can be used on the floor
2. Start at the cleanest part of the room using an "s" or "pull/grab" method, working your way towards the Sterile Ante room

7. ANTE ROOM DAILY CLEANING PROCEDURES

Opening Procedures

1. Clean the door threshold areas with ***PREempt***
2. Clean the vents with ***PREempt***
3. Clean all surfaces with ***PREempt*** (i.e. door handles, sink, soap dispensers, paper towel dispensers, garbage cans, and benches, etc.)
4. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***PREempt***) on the mop starting from the back wall and working your way towards the Exit door, using an "s" or "pull/grab" method
5. Remove trash and place a new bag in each trash receptacle
6. Replace the tacky mats in the buffer areas
7. Take out the trash

Closing Procedures

1. Disinfect all surfaces with ***sterile 70% IPA*** (i.e. sink, soap dispensers, paper towel dispensers, windows, doors and door handles, garbage cans, and benches, etc.)
2. Restock all Sterile Compounding Apparel on the shelves (i.e. gowns, masks, beard covers, hair covers, booties, etc.)
3. Remove trash and place a new bag in each trash receptacle
4. Replace the tacky mats in the buffer areas
5. Take out the trash

8. ANTE ROOM MONTHLY CLEANING

1. Clean the walls, ceiling, and floor with ***Peridox***
2. Clean the vents with ***Peridox***
3. Clean the storage/shelving racks and storage bins with ***Peridox***
4. Clean all surfaces with ***Peridox*** (i.e. door handles, sink, soap dispensers, paper towel dispensers, garbage cans, and benches, etc.)

Procedure: Ceiling

1. Begin at the farthest corner of the room using ***Peridox***
2. Clean all irregular surfaces first
3. Mop with overlapping strokes *Replace Microcinch® mop head as needed*

Procedure: Wall

1. Mop utilizing ***Peridox*** with overlapping strokes down to antimicrobial wall ledge
2. Wipe ledge
3. Mop antimicrobial wall with overlapping strokes down to "baseboard" ledge

4. Finish mopping the wall, with the last foot of wall space not mopped, with horizontal strokes before beginning the floor

Procedure: Floor

1. The same mop **CANNOT** be used for the ceilings/walls can be used on the floor
2. Start at the cleanest part of the room using an "s" or "pull/grab" method, working your way towards the Exit door

9. STERILE ANTE ROOM DAILY CLEANING PROCEDURES

Opening Procedures

1. Clean the door threshold areas with ***Peridox***
2. Clean the vents with ***Peridox***
3. Clean all surfaces with ***Peridox*** (i.e. door handles, sink, soap dispensers, paper towel dispensers, garbage cans, and benches, etc.)
4. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***Peridox***) on the mop starting from the back wall and working your way towards the Ante room door, using an "s" or "pull/grab" method
5. Remove trash and place a new bag in each trash receptacle
6. Take out the trash

Closing Procedures

1. Clean all surfaces with ***Peridox*** (i.e. door handles, sink, soap dispensers, paper towel dispensers, garbage cans, and benches, etc.)
2. Restock all Sterile Compounding Apparel on the shelves (i.e. gowns, booties, gloves, etc.)
3. Remove trash and place a new bag in each trash receptacle

Take out the trash

10. STERILE ANTE ROOM MONTHLY CLEANING

1. Clean the walls, ceiling, and floor with ***Peridox***
2. Clean the vents with ***Peridox***
3. Clean the storage/shelving racks and storage bins with ***Peridox***
4. Clean all surfaces with ***Peridox*** (i.e. door handles, sink, soap dispensers, paper towel dispensers, garbage cans, and benches, etc.)

Procedure: Ceiling

1. Begin at the farthest corner of the room using ***Peridox***
2. Clean all irregular surfaces first
3. Mop with overlapping strokes *Replace Microcinch® mop head as needed*

Procedure: Wall

1. Mop utilizing ***Peridox*** with overlapping strokes down to antimicrobial wall ledge
2. Wipe ledge
3. Mop antimicrobial wall with overlapping strokes down to "baseboard" ledge
4. Finish mopping the wall, with the last foot of wall space not mopped, with horizontal strokes before beginning the floor

Procedure: Floor

1. The same mop **CANNOT** be used for the ceilings/walls can be used on the floor
2. Start at the cleanest part of the room using an "s" or "pull/grab" method, working your way towards the Ante Room door

11. HIGH RISK ROOM DAILY CLEANING PROCEDURES

Opening Procedures

1. Clean the PEC with ***sterile TB1-3300*** followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)
2. Clean the door threshold areas with ***PREempt***
3. Clean the vents with ***PREempt***
4. Clean the work surfaces/cart surfaces with ***PREempt***
5. Clean all high touch surfaces with ***PREempt*** (i.e. door handles, chair seats, backs, and adjustment knobs, clipboards, and garbage cans, etc.)
6. Clean the microwave, scale, and other specialty equipment with ***PREempt***
7. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***PREempt***) on the mop starting from the back wall and working your way towards the Ante room door, using an "s" or "pull/grab" methodhe PEC with ***PREempt*** followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)

Closing Procedures

1. Disinfect the PEC with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)
2. Clean the work surfaces/cart surfaces with ***PREempt***
3. Clean the microwave, scale, and other specialty equipment with ***PREempt***
4. Clean the door handles with ***PREempt***
5. Replace sharps containers
6. Place all miscellaneous daily use items back into the appropriate bin
7. Pick up visible trash from floor
8. Remove trash and place a new bag in each trash receptacle
9. Take out the trash

12. HIGH RISK ROOM MONTHLY CLEANING

1. Clean the ceilings, walls, and floors with ***Peridox***
2. Clean the vents with ***Peridox***
3. Clean the storage/shelving racks and storage bins with ***Peridox***
4. Clean all high touch surfaces (i.e. door handles, chair seats, backs, and adjustment knobs, clipboards, and garbage cans, etc.) with ***Peridox***
5. Clean the work surfaces/cart surfaces with ***Peridox***
6. Clean the microwave, scale, incubator, and other specialty equipment with ***Peridox***
7. Clean the outside of hoods with ***Peridox*** as well as wheels of hoods and cords
8. Clean the PECs with ***sterile Peridox***, utilizing the EasyReach® tool, followed by disinfecting with ***sterile 70% IPA*** (top to bottom, back to front, using overlapping strokes)

Procedure: Ceiling

1. Begin at the farthest corner of the room using ***Peridox***
2. Clean all irregular surfaces first
3. Mop with overlapping strokes *Replace Microcinch® mop head as needed*

Procedure: Wall

1. Mop utilizing ***Peridox*** with overlapping strokes down to antimicrobial wall ledge
2. Wipe ledge
3. Mop antimicrobial wall with overlapping strokes down to "baseboard" ledge
4. Finish mopping the wall, with the last foot of wall space not mopped, with horizontal strokes before beginning the floor

Procedure: Floor

1. The same mop **CANNOT** be used for the ceilings/walls can be used on the floor
2. Start at the cleanest part of the room using an "s" or "pull/grab" method, working your way towards the Ante Room door

13. HAZARDOUS STORAGE-125 DAILY CLEANING PROCEDURES

1. Clean the counters with ***Peridox***
2. Clean the pass through with ***Peridox***
3. Attach the Microcinch® mop head to the mop. **Sparingly** use floor cleaner (**Peridox**) on the mop starting from the back wall and working your way towards the Exit door, using an "s" or "pull/grab" method

14. HAZARDOUS CLEANING-124 DAILY CLEANING PROCEDURES

1. Clean the sink with ***Peridox***
2. Clean the carts with ***Peridox***

15. HAZARDOUS CLEANING-124 WEEKLY CLEANING PROCEDURES

1. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***Peridox***) on the mop starting from the back wall and working your way towards the Exit door, using an "s" or "pull/grab" method

16. COMPOUNDING STORAGE AREA-132 CLEANING PROCEDURES

1. Clean the counters with ***PREempt***
2. Clean the carts, surfaces, chairs, and phone with ***PREempt***
3. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***PREempt***) on the mop ***daily, (follow once weekly with water to remove PREempt residue on the floor),*** starting from the back wall and working your way towards the Exit door, using an "s" or "pull/grab" method
4. Restock supplies

17. PHARMACY CHECKING-133 DAILY CLEANING PROCEDURES

1. Clean the checking tables with ***PREempt***
2. Clean the sink with ***PREempt***
3. Attach the Microcinch® mop head to the mop. ***Sparingly*** use floor cleaner (***PREempt***) on the mop ***daily, (follow once weekly with water to remove PREempt***

residue on the floor), starting from the back wall and working your way towards the Exit door, using an "s" or "pull/grab" method

4. Restock supplies

Attachment 3: Competency Assessment: Cleaning and Disinfection Procedures

COMPETENCY ASSESSMENT: CLEANING AND DISINFECTION PROCEDURES

Employee Name: _____Date:_____

Type: ☐ Initial Competency ☐ Ongoing Competency ☐ Other

Cleaning and Disinfections Practices: The qualified evaluator checks each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session of N/O if the activity was not observed.*

Daily Cleaning:	**Y, N, N/A**
Removes trash and straightens up the area to prepare for daily cleaning	
Cleans with the appropriate cleaning tools designated to each room.	
Uses a lint free cleaning pad/wipe to clean all surfaces.	
Correctly identifies the EPA registered one-step bactericidal disinfectant cleaner used daily as well as the EPA registered one-step *sporicidal* disinfectant cleaner and can state the dwell time for each cleaner. **Non-HD PEC - Sterile TB1-3300** (Followed by 70% Sterile IPA in the PECs) Dwell = 1 minute **Non-HD SEC - PreEmpt-Plus.** Dwell = 1 minute **HD PEC - Sterile Peridox** (Followed by 70% Sterile IPA in the PECs) Dwell = 3 minutes **HD SEC- Peridox RTU.** Dwell = 3 minutes	
Understands that cleaning takes place from cleanest to dirtiest, thus the order is: PECs/horizontal work surfaces such as carts and inside pass-throughs/ vents and door thresholds/high touch surfaces/floors.	
Cleans the hood in the correct order: top to bottom, back to front (ie. top, back, sides, iv bar and hooks, camera, items on the deck, deck).	
Cleans all high touch surfaces (i.e. Door handles, chair seats, backs, and adjustment knobs, clipboards, garbage cans, etc.)	
Mops the floor using the "S" or "pull/grab" method, moving toward the exit door.	
Documents all cleaning in the Simplifi program	
Monthly Cleaning:	**Y, N, N/A**
Cleans with the appropriate cleaning tools designated to each room.	
Uses a lint free cleaning pad/wipe to clean all surfaces.	
Cleans the surfaces of the rooms in the correct order: Irregular surfaces of ceilings and walls/ceilings/walls/windows/doors and door frames/vents/exterior surfaces of the PECs including wheels and cords/ all surfaces (includes underside and wheels) of any carts, tables, chairs, trash cans, clipboards, etc.)/shelving racks and storage bins.	
Cleans with the appropriate cleaning solution: **Non-HD PEC - Sterile Peridox** (Followed by 70% Sterile IPA in the PECs) **Non-HD SEC - Peridox RTU**	

HD PEC - Sterile Peridox (Followed by 70% Sterile IPA in the PECs) **HD SEC - Peridox RTU**	
Cleans the ceiling by starting with irregular surfaces first and then mops with overlapping strokes, starting at the farthest corner of the room. Cleans the walls using overlapping strokes from the top of the wall down to the antimicrobial wall ledge, wipes the wall ledge, and then continues to mop the wall, with overlapping strokes, down to the baseboard ledge. Mop below the baseboard ledge with horizontal strokes before starting on the floor.	
Mops the floor, with a new mop head, using the "S" or "pull/grab" method.	
Uses fresh wipes and mop heads/mop head covers as needed throughout the cleaning process and changes them if they become visibly soiled.	
Rewets the wipe, tool cover, and mop head or cover to ensure that all surfaces being cleaned are uniformly wet enough to achieve the specified dwell time.	
Documents all cleaning in the Simplifi program.	

CHARTWELL Pharmacy

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Sterile Compounding Questionnaire

Section 2: Sterile Compounding Questions

Question 19: If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

- *See attached policy*
  - *OPS056 titled "Shipping and Cold Chain Management".*

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CHARTWELL Pharmacy

TITLE: SHIPPING AND COLD CHAIN MANAGEMENT	POLICY NUMBER: OPS056
URAC STANDARDS: P-OPS 8-1, P-OPS 8-2, P-OPS 8-3, P-OPS 8-4, P-OPS 8-5, P-OPS 8-6	ACHC STANDARDS: DRX5-11A, DRX5-11B, DRX7-9B, DRX7-9C, DRX7-10B
TJC STANDARDS: MC.04.13.01 EP1 & EP4	
EFFECTIVE DATE: 1/1/2021	REVISION DATE: 9/1/21, 9/1/22, 1/11/24, 1/11/25
REVIEWED DATE: 5/1/21, 5/1/22, 9/1/22, 1/11/24, 1/11/25	APPROVAL AUTHORITY: KATHLEEN PATRICK, PRESIDENT

I. POLICY

This policy ensures that medications are packaged and delivered to patients in stable condition. The organization ensures that quality pharmaceutical products are received by the patient in a timely manner under controlled conditions. Packing procedures and materials are used to protect the integrity, sterility, and stability of the CSPs, while also protecting the staff from exposure when transporting CSPs.

II. DEFINITIONS

Cold chain is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range for pharmaceutical drugs.

Undue delay means that the package is not delivered within the expected timeframe

III. PROCEDURES

Please note, the following tasks should be completed prior to preparing to ship the medication:

1. Ensure that all Compounded Sterile Product (CSPs) are labeled with beyond-use dates and storage instructions and disposal instructions for expired medications.
2. The organization informs the patient or recipient of the need for a properly functioning refrigerator or freezer as required for CSP storage. The patient's or recipient's confirmation that the proper refrigerator is documented.

A. Shipping

1. The Pharmacy ensures that quality pharmaceutical products are received by the patient in a timely manner under controlled conditions.

2. Every attempt shall be made to expedite delivery of medication to the patient.
   a. Patients, caregivers and/or prescribers are notified when equipment/supplies will be delivered.
   b. The Pharmacy is focused on ensuring that the patient receives their medication and prior to administration date.

3. Compounding staff communicate handling and exposure instructions to each transporter and attach the instructions to the exterior packaging of the CSP. The mode of transportation is assessed to ensure that integrity, sterility, and stability of the CSP is maintained.

4. Temperature and light sensitive medications will be shipped appropriately following recommended storage guidelines allowing arrival of medication in an appropriate time frame, based on manufacturers' recommendations.

5. If possible and within reason, the medication will be delivered in conjunction with other products dispensed by the pharmacy.

6. The pharmacy will maintain a copy of the patient's signature indicating receipt of the medication.
   a. The signature is obtained by the delivery representative, delivery vendor and documented on the delivery ticket. Signatures may be obtained through UPS, on the delivery tickets, and by any written correspondence.
   b. Records of patient signatures shall be maintained in accordance with company policy.

7. The Pharmacy can track the location of the product(s) after they leave the facility.
   a. Tracking can be completed via shipping software or by telephone for product(s) delivered by Driver or Courier.

8. If changes to scheduled delivery need to be made, a staff member will contact the patient or caregiver. If doses will be missed, or medication will expire prior to use due to changes in delivery, prompt notification to patient/caregiver and prescriber will be made.

9. The organization is committed to providing patients with accurate shipping of their medications, supplies, and educational materials.
   a. Once the medication is visually checked by the pharmacist for accuracy, the medication is placed in a shipping bin and the delivery ticket with barcode is included with the package.
   b. At the shipping station, the delivery address will be cross checked against the shipping vendor's database via the shipping software (UPS World Ship Address Validation).

10. The organization will evaluate on an ongoing basis, the effectiveness and accuracy of its shipping by monitoring timeliness of delivery/turnaround time, shipping errors, and payment responsibilities.

B. Cold Chain Distribution: Process Controls and Monitoring System

1. The pharmacy has documented and implemented a program for management of its cold chain distribution process.

2. Pharmaceutical manufacturers' recommendations for temperate stability ranges will be followed to ensure stability during shipment and delivery.
    a. Products will be packaged appropriately to maintain the appropriate temperature range for 48 hours to ensure the medication is stable when shipped.

3. The pharmacy will select modes of transit/delivery based on the following factors:
    a. Geographic area
    b. Weather conditions
    c. Temperature stability ranges of the medications
    d. Delivery services available in their area; and
    e. Patient/prescriber/caregiver preference

4. The pharmacy will maintain records of shipping incidents via the internal reporting system.

5. The pharmacy has a validated distribution process with the following requirements:
    a. New Packaging Product: When the pharmacy elects to start using a new packaging product designed for cold chain distribution, testing of the new packaging product will be conducted to ensure product stability before implementation.
    b. Testing of cold chain will be completed quarterly, ensuring a variety of temperature ranges are tested.
    c. All cold chain reporting is documented and reviewed during the quarterly Performance Improvement Committee meetings
    d. Correct Packaging: The pharmacy ensures that correct packaging is used for refrigerated and room temperature medications. For more information, please refer to pack-out diagrams/posters in the distribution area.

6. Extreme Weather Delivery Interruption: In the event of extreme weather and expected delivery delays, the pharmacy will consider whether adjustments to packing are necessary, and if so, will make them accordingly.
    a. For more information, please reference Operations Policy: Emergency Preparedness

7. Breakdown in the Distribution Process: In the event of a breakdown in the distribution process that results in lost, stolen or delayed packages, the pharmacy's priority is to ensure that the patient's therapy is not interrupted.

8. Periodic Monitoring of the Cold Chain Distribution Process: The pharmacy conducts testing of its Cold Chain Distribution process when packing product is modified.
    a. When the pharmacy elects to start using a new packaging product designed for cold chain distribution, testing of the new packaging product will be conducted to ensure product stability before implementation.

b. Testing shall be conducted on each packaging product/all box sizes, under different ambient temperature ranges and length of shipping time.
c. Testing occurs quarterly and is documented
d. Results of Cold Chain testing are reviewed by pharmacy operations leadership and shared with the Performance Improvement Committee, for review quarterly.

9. Performance Improvement Program Oversight of the Cold Chain Distribution Process:
   a. The Quality Management Committee shall review the cold chain process annually at a minimum, including when updates to the process are required or when packaging product is modified.
   b. The Quality Management Committee shall evaluate the following:
      1) Validated distribution process with process controls.
      2) Monitoring system
      3) Complaints or concerns related to cold chain shipments raised by a patient or prescriber
      4) Undue Delays: The pharmacy has a process for contacting the patient and the prescriber, if necessary, when an undue delay is encountered in delivering a prescribed drug or device to a patient
      5) Delays may occur for many reasons.

10. A pharmacist will identify whether and when patient care will be affected due to untimely receipt of the medication.
    a. The pharmacist will be responsible for contacting and providing counseling to the patient
    b. The pharmacist will determine if the prescriber needs to be contacted for alternative therapy when the medication is unavailable
    c. All interactions will be documented in the patient progress notes

IV. TRAINING

This policy will be posted on the Company shared drive.

V. APPROVAL HISTORY

Approved By:	Title:	Date:
Kathleen Patrick	President	01/01/2021
Kathleen Patrick	President	05/01/2021
Kathleen Patrick	President	09/01/2021
Kathleen Patrick	President	05/01/2022
Kathleen Patrick	President	09/01/2022
Kathleen Patrick	President	01/11/2024
Kathleen Patrick	President	01/11/2025

CHARTWELL Pharmacy

Chartwell Pennsylvania, LP
1-800-755-4704
1001 Oakdale Road, Oakdale PA, 15071
www.chartwellpa.com

Sterile Compounding Questionnaire

Section 3: Sterile Hazardous Compounding Questions

Question 10: What information is provided to the patient or consumer on the proper handling and disposal of hazardous drug products/containers?

- *See attached patient information*
  - *Hazardous Drug Spill Procedure*
  - *Hazardous Medication Precautions*
  - *Patient Handbook pages 5 and 9*

HAZARDOUS DRUG SPILL PROCEDURE

A hazardous drug spill requires immediate attention.
Follow the procedures listed below to effectively contain a hazardous drug spill.

1. Evacuate patients and personnel from the spill area.
2. Display "Hazardous Drug Spill" sign
3. Apply two gloves to each hand. Put on protective gown, shoe covers, and respirator mask. Refer to the spilled item's Material Safety Data Sheet for additional personal protective equipment recommendations.
4. Without touching the spill, place the absorbent pad, writing side down, over the spill area. Use a second pad if necessary.
5. Once the liquid has absorbed, carefully place the absorbent pads into the biohazard bag.
6. Sweep any broken glass using the scooper/scraper. Dispose of glass and scooper/scraper in biohazard bag.
7. Clean the spill area using the provided cloth towels and a detergent. Rinse twice with clean water. Dispose of cloth towels in biohazard bag.
8. Grabbing the cuff of each of the outer gloves, turn them each inside out and place in the biohazard bag. Keep one glove on each hand.
9. Remove gown, shoe covers and respirator mask and place in the biohazard bag.
10. Seal the biohazard bag using the twist tie and place it inside of the second biohazard bag.
11. Grabbing the cuff of each of the gloves, turn them each inside out and place in second biohazard bag.
12. Seal the biohazard bag using the twist tie and dispose of properly.
13. Wash hands with hot, soapy water.

HAZARDOUS MEDICATION PRECAUTIONS

Proper precautions when using hazardous medications at home is important to your safety. Please call 1-800-755-4704 if you have any questions or concerns at all while receiving this type of medication. We are available 24 hours a day, 7 days a week. In the event of an emergency, always call 911.

What are Hazardous medications?

- These are medications that can affect cell growth or the immune system.

Why do my caregivers need to take special precautions?

- These drugs may be important to your treatment but may cause harm to individuals who do not need them.
- Your body wastes and fluids (including urine, stool, vomit, blood, sweat, semen and vaginal fluids) may also contain some of the drug.
- Your loved ones should follow special precautions for their protection when handling hazardous drugs, body wastes and fluids while you are on treatment and for 48 hours after you have finished treatment.

What should caregivers do to protect themselves?

- The medication should only be handled by the person taking it or the caregiver, if possible.
- Wash your hands before and after handling this medication.
- Wear chemotherapy rated gloves when administering the medications, washing items that are soiled and when disposing of body fluids.
- Wash your hands before putting on the gloves and after removing them.
- Dispose of all needles, syringes and IV equipment in the Sharps container provided.
- Pregnant women, children and pets should never touch the drug, body wastes and fluids or contaminated items.

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Home Infusion & Specialty Pharmacy CHARTWELL PENNSYLVANIA, LP

- If any medication spills, keep others away and clean up the spill right away using the provided spill kit.
- If the spill is on clothing, remove the clothes immediately. Wash the items in the washer with warm water and detergent for 2 cycles.
- If the spill is on a piece of furniture, clean up the spill per directions in the spill kit, then scrub the area with soap and water while wearing gloves.
- If medication gets on the skin, wash and rinse the area using soap and a large amount of water. Call your doctor or nurse if redness or irritation develops.
- While the patient is getting the medication and for 48 hours after, wear gloves when touching body wastes and fluids or contaminated items, such as linens, bedpans or urinals, and items they are throwing away.
- After the patient uses the toilet, always close the lid and flush 2 times.
- Wash reusable containers, such as a urinal or bedpan, with liquid soap or dish detergent and warm water and rinse well. Be careful not to splash yourself or others.
- Always double bag with two plastic bags any contaminated items you are throwing away, such as diapers, ostomy bags, absorbent pads and gloves.

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ORDERS & REFILLS *(continued)*

Enteral Nutrition Patients

Please call and talk to a Chartwell care team member for TEAM 4 <u>one week prior</u> to needing formula and/or supplies. When placing your order, please factor in time for delivery. Orders generally take 3-4 business days to arrive.

PLEASE NOTE: If your formula happens to be out of stock or back-ordered, we will work with you and your doctor to provide an alternative. This is often due to manufacturer delays or supply chain issues that affect providers across the nation.

Home Infusion Patients

It is our goal to supply you with the correct quantity of supplies to administer your infusion therapy. You can help us by providing a correct count of your supplies. Your homecare nurse will teach you how to count and record your supplies each week.

Your Chartwell care team will call you prior to your delivery to confirm inventory and supplies needed for the upcoming week. Chartwell will also call you when medication, equipment and/or supplies will be delivered.

Chartwell is not permitted to automatically refill and dispense, as per regulatory requirements and best practice standards. Deliveries of medication and supplies **<u>will not be completed</u>** unless the patient or their personal representative is spoken with. **We MUST speak with someone before sending refills/supplies. Please be sure to return our calls.**
If you have any questions or concerns about your medicine, please call and talk to a pharmacist.

CHARTWELL STANDARD INFUSION SUPPLIES

STANDARD SUPPLIES

- Alcohol Wipes
- Gloves
- Syringe tip cap (end cap for syringes & tubing)
- Welcome handbook, patient education sheet for administration, and medication information
- Tubing/filters
- Pumps per therapy plan of treatment with batteries & carrying pouch for continuous infusions
- Microclave caps (IV line caps - Neutral Pressure)
- IV pole for gravity & dial-a-flow therapies
- Paper tape
- Saline & Heparin flushes per cath care protocol and patient plan of care
- Vented spike adapter for glass bottles

PERIPHERAL

- IV start kit
- 8in extension tubing (to be changed with each new IV insertion)
- IV Catheter - Insyte w/ wing notch 22gx1in/ 24gx3/4in
- Microclave caps
- (other gauges available upon request)

PICC

- Dressing change kit
- Sorbaview dressing (also a securement device)
- 12in extension tubing (to be changed with each dressing change)

CHEMO

- Chemo spill kit
- Chemo gown
- Chemo gloves
- Chemo mat
- Extra gloves
- Sharps container

PORT

- Dressing Change kit
- Safety Huber needle (no side port)
  - 22G x¾ in
  - 22G x 1 in

AVAILABLE BY REQUEST

• Halogaurd • Statlock• Stockenette • Alcohol caps • Other size IV gauges • Dressing products for allergy and size needs • Port Sorbaview dressing • Betadine and alcohol for chlorhexidine allergy

STORAGE OF SUPPLIES, MEDICATION, FORMULA

- Store all supplies, medication, and formula away from children and pets.
- Do not store supplies on the floor.
- Check the label on all medicine, solutions, and formula for storage instructions.
- If your medicine needs to be refrigerated, please keep it away from food and food spills.
- Refrigerated medicine should be placed in the refrigerator as soon as possible after it arrives.
- Place the new medicine behind previously delivered medicine you may still have in your refrigerator.
- Non-refrigerated items and medicine should be kept in a cool, dry place away from direct sunlight and above freezing temperatures.

Formula Storage

- Formula should be kept in a cool, dry place, away from direct sunlight and freezing temperatures.
- Refrigerate formula immediately after opening.
- Discard any open, unused formula after 24 hours.
- Hang time for formula at room temperature in bag is:
  - 8 hours for adults
  - 4 hours for pediatrics

DISPOSAL OF SUPPLIES, MEDICATION, FORMULA

Do not throw away your infusion/enteral pump or accessories.

Pumps and accessories such as power packs, IV pole clamps, etc. are loaned to you for your home infusion therapy. **Contact the Chartwell DME Department or call 1-800-755-4704, option 2 to arrange for a pump return.**

- Discard all used needles and syringes with needles in a puncture-resistant, hard plastic or metal container. An empty coffee can or empty detergent bottle with a screw-on cap can be used.
  - Close the container with its original lid and secure with heavy duty tape.
  - Place the tightly sealed container in a paper bag and throw it away with your household trash.
  - If you are provided a red sharps container, discard all used needles and syringes with needles in the red sharps container.
- If you are on a chemotherapy medication: Dispose of all gloves, gowns, and used medication containers in the provided yellow sharps container.
- Once your sharps container is 3/4 full (red or yellow), place it in the original paid postage box and take it to your local post office. The box will be shipped to the proper disposal site.
- Discard all drugs, used medication bags/cassettes, syringes without needles, tubing, soiled dressings, bandages, and gloves that were not used for chemotherapy in double-bagged household trash.
- If you need to dispose of any oral medications you received from us that you no longer need, call our specialty pharmacy at 1-800-366-6020. We will mail you a pre-paid envelope to ship your medications to a disposal site to be properly destroyed.

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Sterile Compounding Questionnaire

Section 3: Sterile Hazardous Compounding Questions

Question 11: Describe your initial process for training new employees prior to compounding sterile hazardous drugs.

- *See attached policies*
  - *PH 200 "Personal Training and Evaluation"*
  - *Attachment Aseptic Technique in the hazardous room checklist*
  - *OPS 029 "Disposal of Hazardous Materials/Medical Waste"*
  - *OPS 030 "Handling of Cytotoxic and Hazardous Agents".*

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TITLE: PERSONNEL TRAINING AND EVALUATION	POLICY NUMBER: PH200
TJC STANDARDS: MC.02.01.07 EP 2, 3, 4; MC.02.01.09 EP 2, 3, 4, 5, 6, 7; MC.02.01.11 EP 3, 4, 5, 6; MC.03.01.01 EP 3; MC.03.06.07 EP 1; MC.04.02.03 EP 5	ACHC STANDARDS: DRX7-8N.01, DRX7-8O, DRX7-8O.01, DRX7-8P, DRX7-8Q, DRX7-8Z.02
EFFECTIVE DATE: 1/1/21	REVISION DATE: 9/1/21, 8/1/22, 11/1/23, 11/1/24, 1/2/25
REVIEW DATE: 5/1/21, 5/1/22, 8/1/22, 11/1/23, 11/1/24, 1/2/25	APPROVAL AUTHORITY: KATHLEEN PATRICK

I. POLICY

The designated person or assigned trainer is responsible for ensuring that all new employees who will compound sterile products undergo initial training and competency of core skills followed by validation testing of hand hygiene, garbing, and sterile technique, in both the non-hazardous and hazardous environments, prior to compounding any products for patient use. This validation testing represents the most challenging or stressful conditions encountered by the compounding staff. Frequency of training and competency assessment are outlined below.

II. PROCEDURES

A. Demonstrating Knowledge and Competency of Core Skills

1. Prior to independently preparing CSPs, compounding personnel must complete training and demonstrate knowledge in core skills to prove understanding in how to compound sterile preparations safely and effectively.

2. This training and competency (i.e. didactic training) must be completed initially and every 12 months. Note: This training is in addition to the validation testing noted below.

3. Training and competency must include but is not limited to the topics listed below:

   a. Hand Hygiene
   b. Garbing
   c. Cleaning and Disinfecting
   d. Aseptic Technique
   e. Achieving and/or maintaining sterility
   f. Use of Equipment
   g. Documentation of the Compounding Process
   h. Principles of High-Efficiency Particulate Air (HEPA)-filtered unidirectional airflow within the ISP Class 5 area

i. Proper use of PECs
j. Principles of movement of materials and personnel within the compounding area

B. Overview of Validation Testing

1. All new compounding personnel will be required, initially and every 6 months, to validate the effectiveness of their hand hygiene, garbing, and sterile technique, in both the hazardous and non-hazardous environments, prior to compounding products for patient use.

   a. The designated person may elect to validate technique on a more frequent basis.

2. Testing procedures to assess hand hygiene, garbing and aseptic techniques will be completed by the Designated Person or an assigned trainer using observation following the Hand Hygiene and Garbing Competency Assessment and by confirming negative results from the Gloved Fingertip Sampling procedure, whose guidance is set forth in the United States Pharmacopeia Chapter 797 (USP <797>).

3. Personnel that are only involved with in-process checks or final verifications of CSPs will be required to complete gloved fingertip testing (post garb assessment) and media fill testing annually with their other competency training.

4. Additional personnel not otherwise listed (i.e. not responsible for direct compounding) may be required to undergo additional competencies at the discretion of the DP and/or Pharmacy Director.

5. All results of testing will be documented by individual practice site SOPs.

C. Initial Validation

1. Demonstrating Competency in Garbing and Hand Hygiene

   a. Garbing and Hand Hygiene competency consists of both visual observation (following all procedures outlined in PH104 Attachment 4: Competency Assessment: Hand Hygiene and Garbing) and Glove and Fingertip Testing.
   b. The competency must be completed no fewer than 3 separate times

      i. The 3 successful completions must be in succession – failure to of any of the test require a repeat until 3 evaluations are completed in a row.
      ii. Each of the 3 initial competency evaluations must occur after a separate and complete hand hygiene and full garbing procedure.

   c. Glove Fingertip Sampling

i. Sampling procedures will follow those outlined in USP <797> Section 2.2.
ii. Negative results (no microbial growth) must be obtained from all 3 samples (each sample is one plate per hand) following an incubation period of at 30°C - 35°C for 48 hours and then at 20°C-25°C for 5 additional days.
iii. Successful completion of the gloved finger-tip testing must be completed prior to beginning compounding CSPs or have a direct oversite of compounding personnel.
iv. Should failure of the competency occur, this should be documented and include the required details as outlined in USP<797>.

2. Demonstrating Testing in Aseptic Manipulation

a. Aseptic Manipulation evaluations consist of visual observation, media-fill, GFT of both hands and surface sampling of the direct compounding area.
b. Media Fill Testing

i. Testing procedures for assessing sterile technique will be accomplished using Media-Fill Challenge Test Kits based upon the most difficult compounded sterile product that the individual is to mix in both the hazardous and non-hazardous environments.
ii. If the personnel compounds only sterile to sterile products, then the media fill test can be conducted only utilizing sterile components.
iii. If the personnel compounds non-sterile to sterile products, then the media fill test must be conducted using non-sterile components.

c. Upon completion of the Media Fill Challenge Kit, the personnel must have their fingertips sampled from both hands INSIDE AN ISO CLASS 5 PEC.

i. Post Mixing Gloved Fingertips will be incubated as per all fingertip testing, but this test cannot have more than 3 CFUs on both plates combined.

d. Upon completion of the Media Fill Challenge Kit, the personnel's direct compounding area must be sampled (i.e. surface sampling)

i. Post mixing surface samples must not exceed 3 CFUs per plate. All other surface sampling procedures must be followed for post mixing surface sampling.

e. Media Fill Tests samples will be incubated at 20°C to 25°C or at 30°C to 35°C for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, the filled containers will be incubated for at least 7 days at each temperature. Failure is indicated by visible turbidity or other visual manifestations of growth in any sample on or before day 14.

f. A failure of any part of the media fill testing (Media Fill test kit growth, post mixing gloved fingertip and surface sampling exceeding CFU counts) will deem the entire aseptic manipulation competency as failed. Both demonstrations are required to be passed prior to compounding.

   i. Should failure of the competency occur, this should be documented and include the required details as outlined in USP <797>.

D. Ongoing Validation

1. Gloved Fingertip Testing (Post Garbing Assessment)

   a. Garbing and Hand Hygiene competency consists of both visual observation (following all procedures outlined in PH104 Attachment 1: Competency Assessment: Hand Hygiene and Garbing) and Glove and Fingertip Testing.
   Note: The competency only needs to be completed ONCE for ongoing validation.
   b. Negative results (no microbial growth) must be obtained from the sample (one plate per hand) following an incubation period of at 30°-35°C for 48 hours and then at 20°C-25°C for 5 additional days. If any of the sample tests positive (e.g., any CFUs are present), test must be repeated before being allowed to compound sterile preparations.

2. Media Fill Testing

   a. Ongoing validations will follow the same procedures as the Initial Validation Media Fill Test.

E. Media Fill Test Kits

1. Preferably, Media fill test kits will be based off commercially available kits that have a Certificate of Analysis associated with them.
2. Procedures for the media fill test will be developed by each individual practices site's designated person and placed into their SOPs.

F. Testing Plates

1. Plates (or paddles for gloved fingertip testing) must contain general microbial growth agar (e.g., trypticase soy agar [TSA]) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80)
2. Testing shall be completed per the manufacturer's specifications.

G. Personnel that conduct any validation testing must be training according to each site's SOPs

H. Should failure occur and/or serious gaps in aseptic technique be identified, the designated person will be notified to facilitate additional training/reorientation with further mitigation as appropriate.

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III. APPROVAL HISTORY

Approval Authority	Title	Date
Kathleen Patrick	President	01/01/2021
Kathleen Patrick	President	05/01/2021
Kathleen Patrick	President	09/01/2021
Kathleen Patrick	President	05/01/2022
Kathleen Patrick	President	08/01/2022
Kathleen Patrick	President	11/01/2023
Kathleen Patrick	President	11/01/2024
Kathleen Patrick	President	01/02/2025

Aseptic Technique in the Hazardous Room Checklist

This competency focuses on a demonstration of knowledge and behaviors that reduce the risk of contamination throughout common activities during the aseptic compounding process while working in the hazardous environment. It also focuses on a demonstration of knowledge and behaviors that ensure proper personnel hygiene habits, hand washing and garbing as well as use of personal protective equipment (PPE).

Competencies:	Satisfactory (✓/X)
Exits the main compounding room and enters the Hazardous Ante Room.	
Is aware of the line of demarcation separating clean and hazardous sides and observes required activities.	
Dons a second pair of shoe covers or a pair of shoe covers over designated clean area shoes one at a time, placing the covered shoe on the hazardous side of the line of demarcation, as appropriate.	
Dons a second gown (chemo) by selecting the appropriate size and examining for any holes, tears, or other defects and ensure full closure.	
Dons a second appropriate size sterile (chemo) gloves ensuring that there is a tight fit with no excess glove material at the finger tips with no defects, holes, or tears.	
Routinely disinfects gloves and items with 70% sterile alcohol prior to working in the direct compounding area and after touching items or surfaces that may contaminate gloves.	
Works 6 inches in the hood, placing only arms and hands in the work area.	
Ensures syringes, needles and tubing remain in their individual packaging and are opened in ISO Class 5 work area.	
Disinfects all points of entry every time and allows sufficient time to dry.	
Does not block inlet grid with supplies and debris (BSC cabinet only). When entering vials and bags ensure needle is on a 45 degree angle with bevel up.	
Uses scooping method when recapping needle is necessary.	
Cleans spills between orders.	
Does not block air flow with hands when manipulating vials or adding to bag.	
Avoids touching critical areas of syringe (needle, hub, barrel).	
Labels products outside of the hood/Labels products correctly.	
Disposes of sharps and waste according to institutional policy or recognized guidelines.	
Removes chemo gown and chemo gloves on the hazardous side of the Hazardous Ante Room.	
Removes shoe covers one at a time, ensuring that uncovered foot is placed on the clean side of the line of demarcation.	
Removes gown and discards it.	
Removes gloves and performs hand hygiene.	
Exits the Hazardous Ante Room into the Ante Room.	
Removes and discards mask, head cover, and beard cover, if used.	
Removes shoe covers one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation. Removes and discards shoe covers every time the compounding area is exited.	

Aseptic Technique in the Hazardous Room Checklist (cont.)

Person Being Tested: _____
Facility: _____
Observed On: _____
Observed By: _____
Notes:

***The examinee should be immediately informed of all unacceptable practices and informed of and demonstrated correct practices.

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CHARTWELL Pharmacy

TITLE: DISPOSAL OF HAZARDOUS MATERIALS/MEDICAL WASTE	POLICY NUMBER: OPS029
URAC STANDARDS: PM 5-1, P-OPS 5-2,	ACHC STANDARDS: DRX1-1B, DRX1-7A, DRX4-6A, DRX4-8A, DRX5-5A, DRX5-5B, DRX7-1A, DRX7-2A, DRX7-2B, DRX7-6A, DRX7-6B, DRX7-8Z.02, DRX7-8Z.10, TCRX6-A, TCRX6-B, TCRX7-J, DRX11-I, HDH10-A
TJC STANDARDS: EC.02.02.01 EP 2	
EFFECTIVE DATE: 1/1/2021	REVISION DATE: 9/1/21, 10/1/24, 6/1/25
REVIEWED DATE: 5/1/21, 9/1/21, 5/1/22, 10/1/24, 6/1/25	APPROVAL AUTHORITY: KATHLEEN PATRICK, PRESIDENT

I. POLICY

The organization is responsible for proper disposal of hazardous materials and medical waste generated in the pharmacy and in the patient's home. Staff assigned to clean and remove hazardous waste are trained in safe practices that protect themselves and others and prevent contamination. Storing, handling, disposal and record keeping will be in accordance with all local, state, and federal regulations.

II. DEFINITIONS

A. Culture and Stocks: Culture and stocks of infectious agents and associated biological, including cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; waters from the production of biological; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

B. Pathological Wastes: Human pathological wastes, including body fluids that are removed during medical procedures, and specimens of body fluids and their containers.

C. Human Blood and Blood Products: Liquid waste blood, products of blood, items saturated and/or dripping with human blood, or items that were saturated and/or dripping with human blood that are now caked with dried human blood, including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing, and laboratory analysis or the development of pharmaceuticals. Intravenous bags are included in this category.

D. Sharps: Sharps that have been used in patient care, including hypodermic needles, syringes (with or without attached needles), pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as slides and cover slips.

E. Isolation Wastes: Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases.

F. Unused Sharps: Unused, discarded sharps, hypodermic needles, syringes, and scalpel blades.

G. RCRA Hazardous Pharmaceuticals: RCRA (Resource Conservation and Recovery Act) Hazardous Pharmaceuticals include bulk chemotherapy in which more than trace amount is remaining in the container, and empty vials, syringes, IV bags, and tubing that contained P listed or U listed IV Products (listed in appendix A).

H. Trace Chemotherapeutic Wastes: Chemotherapeutic waste (also called antineoplastic and cytotoxic wastes) is defined as all products resulting from the compounding and/or administration of cytotoxic agents and is now recognized as a potential hazard to pharmacists, nurses, and any other personnel that may meet these agents. Only containers with "trace amount" of drug remaining may be disposed of in this container.

III. PHARMACY PROCEDURES

A. All sharps waste will be collected and disposed of in a leak proof, puncture resistant rigid container that is labeled as hazardous waste and meets Department of Transportation (DOT) regulations for hazardous waste containers. All non-sharps hazardous waste, including components of a needless system, can be collected in either a rigid or non-rigid (red bag) container unless prohibited by state regulations.

B. All RCRA waste that is generated in the pharmacy will be disposed of in a rigid Black RCRA bin.

C. All trace Chemotherapeutic Waste that is generated in the pharmacy will be disposed of in a rigid Yellow Chemotherapy bin.

D. As the rigid containers are filled, they will be immediately collected in a timely manner from the compounding area and placed into an area of the warehouse designated for storage of hazardous materials for proper disposal.

E. The pharmacy maintains a segregated area for storage of regulated waste pending destruction.

F. A contract with a hazardous waste disposal firm and/or Sharps mail away program will be established by the organization. The contract firm must indicate how and where the waste is being disposed of and a hazardous waste manifest must be supplied by the firm when picking up the waste. Upon destruction, a completed manifest must be returned to the organization and maintained to document destruction. Records must be kept for 7 years.

G. The pharmacy is responsible for the cost of shipping and cost of disposal.

IV. PATIENT PROCEDURES

A. Chemotherapeutic waste that is generated in the patient's home will be placed back into the zipper-lock plastic bag that it was delivered in. This bag is then placed into the puncture proof HD container.

B. Enough containers will be made available to prevent overfilling and will be sent to patients under long term care.

C. Needle cutting and recapping will be avoided due to the potential to cause injury. If recapping is required, a single hand technique is to be used.

D. In the patient's home, all hazardous materials and medical waste, including sharps, will be placed in a rigid, puncture proof or HD container. When the container is full, the patient will be instructed to seal the puncture proof container and place it in the DOT approved boxes (see below).

1. When the initial supplies are shipped to the patient's home, a DOT approved box or boxes (assume storage for 2 weeks prior to pick-up) will also be shipped. This box will be a rigid, fiberboard box and contain one 200 lb. burst strength polyethylene or equivalent bag (hazardous waste disposal bags meet the intent).
2. The following information is included on the DOT approved disposal boxes:
    a. The box will be marked with a water-resistant universal bio-hazardous symbol
    b. The generator name and company name, address, phone number
    c. The transporter's name, address, and phone number (i.e. United Parcel Service etc.)
    d. The disposal company's name, address, and phone number
    e. Date of shipment
    f. Security seal
3. The patient is encouraged to contact the mail away program for destruction (instructions included within the DOT approved box).

E. Pick-ups and deliveries will be handled by the company or other acceptable service capable and willing to handle such wastes.

F. The pharmacy is responsible for the cost of shipping and cost of disposal related to the DOT approved destruction boxes.

V. APPROVAL HISTORY

Approved By:	Title:	Date:
Kathleen Patrick	President	01/01/2021
Kathleen Patrick	President	05/01/2021
Kathleen Patrick	President	09/01/2021
Kathleen Patrick	President	05/01/2022
Kathleen Patrick	President	10/01/2024
Kathleen Patrick	President	06/01/2025

By signing below, I indicate I have reviewed and approved of this policy:

Altoona Pharmacist in Charge	06/10/25 Date
Altoona Hazardous Drug Designated Person	06/10/25 Date
Altoona USP <797> Designated Person	06/09/25 Date
Erie Pharmacist in Charge	06/09/25 Date
Erie Hazardous Drug Designated Person	06/09/25 Date
Erie USP <797> Designated Person	06/09/25 Date
Oakdale Pharmacist in Charge	06/09/25 Date
Marissa Davis (Jun 9, 2025 12:32 EDT) Oakdale Hazardous Drug Designated Person	06/09/20 Date
Jessica Norris (Jun 12, 2025 10:27 EDT) Oakdale USP <797> Designated Person	06/12/25 Date

APPENDIX A

P-LIST DRUGS IN INVENTORY:

Arsenic Trioxide

Epinephrine

U-LIST DRUGS IN INVENTORY:

Cyclophosphamide

Mitomycin C

Multi-trace 5 Concentrate

Selenious Acid

Tralement

APPENDIX B

SHARPS/ BIOHAZ. (also known as Regulated Medical Waste) *Red Containers*		***CHEMO*** *Yellow Containers*	***RCRA HAZARDOUS Black Bin or Black Sharps***	***NON-REG. TRASH*** *Gray, White and Others*
Puncture Proof Container	BioHaz	CHEMO	**RCRA**	Municipal Trash
- Needles - Broken Glass - Ampules - Other sharps	- Non-chemo vials - IVIG vials/bags - Albumin vials/bags - Blood factor vials - Syringes For non-sharp related biohazard waste, may be disposed of in Red Biohazard Bag.	- Trace Chemo - Empty RCRA Chemotherapy vials and syringes except P-list drug containers - Chemo packaging - Chemo mats not involved with spills - Chemo gloves, gowns, masks and shoe covers	- Bulk chemotherapy, P list or U list drugs (more than a trace amount remaining) - Empty vials, IV bags, and tubing that contained P listed IV Products - Anything used to clean up a RCRA or chemotherapy spill	- Non-med IV fluids (NS, LR, D5LR) can be drained in sink - Packaging - IV wraps - Syringe packaging - Gauzes - Gowns - Masks - Paper - Labels, etc.

References:
United States Pharmacopeia (2020). General Chapter, ⟨800⟩ Hazardous Drugs—Handling in Healthcare Settings. USP-NF. Rockville, MD: United States Pharmacopeia.

C.M. Clancy, Department of Environmental Protection (personal communication, August 20th, 2024).

OPS029 Disposal of Hazardous Materials Medical Waste

Final Audit Report 2025-06-12

Created:	2025-06-09
By:	Lori Tinlin (lori.tinlin@carepathrxllc.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAbihC2snDlZ_q3P2PYC2k0aNNcFr3gYr-

"OPS029 Disposal of Hazardous Materials Medical Waste" History

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Agreement completed.
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CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

CHARTWELL Pharmacy

TITLE: HANDLING OF CYTOTOXIC AND HAZARDOUS AGENTS	POLICY NUMBER: OPS030
URAC STANDARDS: P-OPS2-4, P-OPS5-2	ACHC STANDARDS: DRX1-7A, DRX7-2A, DRX7-6A, DRX7-6B, DRX7-8F.01, DRX7-8Z.02, DRX7-8Z.04, DRX7-8Z.09, DRX7-8Z.13, DRX7-8Z.14, TCRX7-B, TCRX7-D
TJC STANDARDS: MC.02.01.01 EP 3; MC.04.02.01 EP 5; MM.01.01.03 EP 1, 2; EC.02.02.01 EP 1, 2, 11	
EFFECTIVE DATE: 1/1/2021	REVISION DATE: 9/1/21, 9/1/22, 11/1/22, 4/15/24, 5/1/25
REVIEWED DATE: 5/1/2021, 9/1/21, 9/1/2022, 11/1/22, 4/15/24, 5/1/25	APPROVAL AUTHORITY: KATHLEEN PATRICK, PRESIDENT

I. POLICY

The organization has the permits, licenses, manifests, and safety data sheets required by law and regulation for managing hazardous materials and waste. Cytotoxic or hazardous agents are to be handled according to current standards of practice to minimize the risk of exposure to staff, patients, and the environment. **Access to areas where HDs are handled is restricted to authorized personnel to protect others not involved in HD handling.** The handling of these agents will be carried out in a manner consistent with the recommendations including but not limited to the National Institute for Occupational Safety and Health (NIOSH), USP <800>, OSHA, accrediting bodies, as well as state, federal and local laws. All staff are advised of the risks to their reproductive systems when handling hazardous medications and confirm in writing that the risks are understood.

Refer to the Hazardous Drug (HD) List for current drug handling precautions located in the designated work areas or on the company's shared drive. Hazardous drugs that are not categorized should be handled at the highest risk level.

II. PROCEDURES

A. Exposure

1. The main routes of exposure to cytotoxic and hazardous agents are through:

    a. Absorption through skin of mucous membranes after contact with drugs or contaminated work surfaces
    b. Injection by inadvertent needle stick
    c. Inhalation of drug aerosols
    d. Ingestion through contaminated food, beverage, tobacco products or other hand to mouth behavior

2. A backup generator acts as an uninterrupted power source for the ventilation systems of negative pressure compounding and storage areas, as well as other key operational systems, in order to limit exposure and spread of HD residue.

3. Proper PPE is required; please see pharmacy policy on *Aseptic Compounding Considerations* and associated attachments for more details.

4. Exposure of personnel may occur during:

    a. Receipt
        - Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors

    b. Dispensing
        - Counting or repackaging tablets and capsules

    c. Compounding and Other Manipulations
        - Constituting or reconstituting powdered or lyophilized HDs
        - Withdrawing or diluting injectable HDs from parenteral containers
        - Expelling air or HDs from syringes
        - Contacting HD residue present on PPE or other garments
        - Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs
        - Maintenance activities for potentially contaminated equipment and devices
        - Priming IV tubing

    d. Administration
        - Generating aerosols during administration of HDs by various routes
        - Priming an IV administration set
        - Patient-care activities
        - Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials

    e. Spills
        - Spill generation, management, and disposal

    f. Transport
        - Moving HDs within a healthcare setting

    g. Waste
        - Collection and disposal of hazardous waste and trace contaminated waste

B. Receiving and Storage

1. Unpacking HDs from their external shipping containers occurs in a negative or neutral pressure area and is prohibited from occurring in sterile compounding areas. PPE must be worn when unpacking HDs in the designated space per USP <800>.

a. Chemotherapy gloves that meet the American Society for Testing and Materials (ASTM) standards
b. Chemotherapy gown made of polyethylene-coated polypropylene or other laminate non-permeable material. The gown must be back closing, long sleeved, have closed elastic or knit cuffs, and must be without seams or closures that could allow HDs to pass through.
c. Appropriate respiratory protection required
d. Examine the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass).

2. Damaged containers should be treated as a spill. See below procedures and follow Pharmacy Policy on *Emergency Procedures for Cytotoxic and Hazardous Drug Spills* for more information.

    a. If the shipping container appears damaged, follow the procedure outlined below:
        - Seal container without opening and contact the supplier.
        - If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous Material"
        - If the supplier declines return, dispose of as hazardous waste

    b. If a damaged shipping container must be opened, follow the procedure outlined below:
        - Seal the container in plastic or an impervious container.
        - Don all appropriate PPE including NIOSH approved respirator.
        - Transport the container to a biological safety cabinet and place it on a plastic-backed preparation mat.
        - Open the package and remove undamaged items.
        - Wipe the outside of the undamaged items with an approved decontamination wipe.
        - Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous Material".
        - If the supplier declines return, dispose of as hazardous waste.
        - Deactivate, decontaminate, and clean the biological safety cabinet as outlined in Pharmacy Policy on *Cleaning and Disinfecting of the Compounding Area*
        - Discard the mat and cleaning disposables as hazardous waste.

3. A disposable plastic backed mat may be placed on the receiving surface to protect it from hazardous material.

4. Place each drug in a chemotherapy bag (multiple containers of the same drug can be placed in the same bag)

5. HDs must be delivered to the HD storage area immediately after unpacking.

6. A Spill Kit is available in the receiving area should a spill occur during or prior to unpacking deliveries.

    a. Refer to policy and procedure Pharmacy Policy on *Emergency Procedures for Cytotoxic and Hazardous Drug Spills* for more information.

7. HDs are stored in a negative pressure room.

8. HDs are stored in a manner to minimize the chance of breakage and contain any accidental leakage.

9. HDs (as well as all other drugs) are prohibited from being stored on the floor.

10. The storage room for HD medications that require manipulation other than counting and repackaging final dosage forms must meet the following requirements:

    a. It is an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).
    b. Refrigerated antineoplastic HDs stored within must have a dedicated refrigerator.

C. Drug Preparation

1. A Biological Safety Cabinet (BSC) must be used to protect against drug aerosolization during Preparation. Pre-administration activities, such as spiking the HD bag and priming of the administration set should occur in the BSC to reduce exposure risk.

2. Safety Data Sheets (SDS) for each antineoplastic agent are accessible to all employees. The method for using the SDS website is located on the company's shared network.

3. A Closed System Transfer Device (CSTD) may be used to minimize the escape of hazardous drug or vapor concentrations outside the system when dosage form allows. Personal protective equipment (PPE) during drug preparation follows USP <800> guidelines and is based on facilities assessment of risk. PPE includes:

    a. Gloves
        - Chemotherapy gloves must be worn for handling all HDs.
        - When used for sterile compounding, the outer chemotherapy gloves must be sterile.
        - Gloves should be changed every 30 minutes or between preparations, whichever is shorter. Also, gloves must be changed when torn, punctured, or contaminated.
        - Hands must be washed with soap and water after removing gloves.

    b. Gowns
        - Disposable gowns made of polyethylene-coated polypropylene or other laminate material must be worn when compounding HD's. Gowns must be back closing, long sleeved, have closed elastic or knit cuffs, and must be without seams or closures that could allow HDs to pass through.
        - Gowns must be changed per the manufacturer's information for permeation of the gown or immediately after a spill or splash.
        - Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.

    c. Head, Hair and Shoe Covers

- Head, hair covers (including beard and moustache, if applicable) and shoe covers provide protection from contact with HD residue.
- When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC to avoid spreading HD contamination and exposing other healthcare workers

4. Additional guidelines relating to drug preparation and administration may be found in Pharmacy Policy *Compounding Cytotoxic and Hazardous Drugs*.

D. Drug Dispensing

1. Intact tablets or capsules

   a. Tablets or capsules are not to be opened, crushed or split prior to dispensing.
   b. A single pair of chemotherapy gloves must be worn for handling all enteral HDs
   c. A dedicated counting tray and spatula will be used for all Hazardous medications.
      - The tray must be decontaminated after each use by lightly misting a sterile cloth with Peridox solution and wiping the tray. Allow to dry for 5 minutes then wipe clean with 70% isopropyl alcohol. Allow to dry for at least 5 minutes prior to continuing use.

2. IV solutions

   a. Proper preparation for dispensing the final product to the patient is detailed in Pharmacy Policy *Compounding Cytotoxic and Hazardous Drugs*.

E. Drug Labeling

1. All HDs must be clearly labeled with the drug identity and the appropriate HD warning during transport, storage, and final dispensed product/compounded sterile preparation (CSP).

F. Drug Delivery

1. Refer to Pharmacy Policy on *Dispensing and Delivery of Cytotoxic and Hazardous Drugs*.

G. Drug Administration

1. When administering hazardous agents, it is recommended that a protective, non-absorbent, disposable, lint-free gown be worn with gloves pulled up over the cuffs.

2. The use of disposable plastic-backed liners is recommended in the area of administration which protects the patient and the environment from exposure during any accidental spill.

3. CSTDs must be used for administration of HDs when the dosage form allows as well as use of needleless connectors.

H. Additional guidelines for chemotherapy administration can be found in nursing policies and procedures. Refer to Nursing Policy on *Antineaplostic Therapy Guidelines*.

1. Refer to pharmacy Operations Policy on *Disposal of Hazardous Materials-Medical Waste*.

I. Hazardous Drug Spills

1. Refer to Operations Policy on *Disposal of Hazardous Materials-Medical Waste* for guidelines regarding emergency procedures for cytotoxic and hazardous drug spills.

J. Accidental Exposures

1. Any accidental exposure to a hazardous drug requires immediate intervention.

2. In the event of an exposure:
   a. Remove the contaminated gloves and/or gown
   b. Cleanse exposed skin with soap and water
      - For eye exposure, flush eyes with water or saline for at least 15 minutes
      - For needle sticks, let the wound bleed freely and cleanse.
   c. Report exposure to your supervisor
   d. Seek immediate medical attention

K. Medical Surveillance

1. The company will participate in a Medical Surveillance Program which requires that all employees who administer chemotherapeutic drugs or who have routine contact with chemotherapeutic drugs, be given the opportunity to receive a medical evaluation and lab work annually as per Employee Health.

L. Education and Training

1. Training and documentation of training for employees must occur during initial orientation and prior to independently handling HDs and be reassessed annually. For more information see Pharmacy Policy on *Aseptic Compounding Considerations*.

2. All staff who handle HDs must be trained based on their job functions (ex: in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs)

3. See Pharmacy Policy on *Hazardous Communication Program* for details on explicit trainings.

III. APPROVAL HISTORY

Approved By:	Title:	Date:
Kathleen Patrick	President	01/01/2021
Kathleen Patrick	President	05/01/2021
Kathleen Patrick	President	09/01/2021
Kathleen Patrick	President	09/01/2022

Kathleen Patrick	President	11/01/2022
Kathleen Patrick	President	04/15/2024
Kathleen Patrick	President	05/01/2025

By signing below, I indicate I have reviewed and approved of this policy:

Altoona Pharmacist in Charge	05/27/2025 Date
Altoona Hazardous Drug Designated Person	05/27/2025 Date
Altoona USP <797> Designated Person	05/27/2025 Date
Erie Pharmacist in Charge	05/28/2025 Date
Erie Hazardous Drug Designated Person	05/27/2025 Date
Erie USP <797> Designated Person	05/27/2025 Date
Oakdale Pharmacist in Charge Alexander E Ameredes (May 27, 2025 15:07 EDT)	05/27/2025 Date
Oakdale Hazardous Drug Designated Person Marissa Davis (May 28, 2025 10:49 EDT)	05/27/2025 Date
Oakdale USP <797> Designated Person Jessica Norris (May 27, 2025 13:15 EDT)	05/27/2025 Date

IV. REFERENCES

USP Compounding Compendium, <800> Hazardous Drugs-Handling in Healthcare Settings, 2020.

Nickel B, Gorski L, Kleidon T, et al. Infusion Therapy Standards of Practice, 9th Edition. J Infus Nurs. 2024;47(1S Suppl 1):S1-S285. doi:10.1097/NAN.0000000000000532

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

			Inspection Information
Business e-Profile ID:	802348		
Legal Business Name:	Chartwell Pennsylvania, LP	**Conference Call Date:**	5/20/2024
Doing Business As (DBA):	Chartwell Pennsylvania	**Start Time: 24-hour format (13:00)**	8:35
Address:	1001 Oakdale Road	**End Time: 24-hour format (13:00)**	11:38
City:	Oakdale	**Onsite Inspection Date(s):**	5/21/2024
State:	Pennsylvania	**Start Time(s): 24-hour format (13:00)**	8:02
Zip Code:	15071	**End Time(s): 24-hour format (13:00)**	16:16
Telephone number:	412-920-7500	**Inspector Name(s):**	Howard Kramer RPh
Toll free number:	800-755-4704	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	412-920-2830/412-920-1869	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.chartwellpa.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy- 1.00, 47.06, and 47.07

Sterile- 56.0, 56.2, and 86.0

Additional information on NABP's Inspection website.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	8:00	17:30	
Tuesday	8:00	17:30	
Wednesday	8:00	17:30	
Thursday	8:00	17:30	
Friday	8:00	17:30	
Saturday	9:00	15:00	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Eric Schaefer	schaefereg2@upmc.edu	301063
Nonsterile Designated person(s)	N/A	N/A	N/A
Sterile Designated person(s)	Eric Schaefer	schaefereg2@upmc.edu	301063
Hazardous Designated person(s)	Eric Schaefer	schaefereg2@upmc.edu	301063

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Jessica Norris	Lead Pharmacist	Y
2	Marissa Davis	Supervisor of Pharmacy Operations	Y
3	David Benedict	Chief Operations Officer	Y
4	Lori Tinlin	Manager of Accreditation	N/A
5	Megan Zielke	Medication Safety Pharmacist	Y
6	Anita Phillips	Pharmacist	Y
7	Marla Slesinger	Pharmacist	Y
8	Vicky Andrew	Pharmacist	Y
9	Amberly Morningstar	Pharmacist	Y
10			

In addition to the above, there were 10 pharmacists, 19 technicians, 13 dispatchers and drivers, 8 warehouse assistants and buyers, and 6 DME coordinators.

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Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Pennsylvania State Board of Pharmacy	Chartwell Pennsylvania, LP	Pharmacy	PP414443L Exp: 8/31/2025
Drug Enforcement Administration	Chartwell Pennsylvania, LP	Controlled Substance - Pharmacy	BC6529157 Exp: 8/31/2026
Pennsylvania Department of Health	Chartwell Pennsylvania	Distributor(Prescription)	3000008555 Exp: 2/28/2025
Pennsylvania Department of Health	Chartwell Pennsylvania	Wholesaler/Distributor	8000002169 Exp: 2/28/2025

Inspector Notes: Non-resident licenses are held in AK, AZ, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KY, LA, ME, MD, MI, MN, MS, MO, MT, NE, NH, NJ, NM, NC, ND, OH, PA, RI, SC, SD, TN, UT, VT, VA, WA, WV, WI and WY. Chartwell Pennsylvania is a home infusion and specialty pharmacy operating as an affiliate of the University of Pittsburgh Medical Center (UPMC). The pharmacy has a contractual agreement with a managed services organization, CarepathRx LLC, located in the same building but with a different address, which performs data entry, DUR, and claim adjudication. UPMC is a minority owner of CarepathRx and a majority owner of Chartwell Pennsylvania. The facility holds wholesale distributor licenses which have not been utilized in recent years. Insulin is stocked, however, there was no ReliOn insulin observed. No platforms are used that are a marketplace for pharmacies to buy, sell, and bid on overstock and short-date drugs, and no price labels for any such platforms were observed. There is no semaglutide compounded. The PIC was not available for the inspection, and personnel files for sterile compounding training were locked in his desk and therefore unavailable for review by this inspector. Some training requirements are marked missing in the <797> Records Review as the personnel files were not available at the time of this inspection. Please see Doc01_PI_InspectorNotes for the Certificate of Analysis for an API used in compounding. There are no biologicals compounded. Please see Doc02_PI_InspectorNotes for the list of white bagged drugs and sample labels for two of the white bagged prescriptions. White bagged drugs are shipped only to UPMC provider's offices, and not to pharmacies. The latest environmental monitoring report dated 2/20/2024 indicated no microbes were found. ProficientRx is not a current source of product. HC Pharmacy Central Inc, a UPMC warehouse, will be dissolved effective 1/1/2025. David Benedict, COO, stated this source will no longer be used effective immediately. The Baxter Healthcare Exactamix recalled products, Pro 1200 and Pro 2400, are not used at this pharmacy. The Exatamix products used here were not subject to the recall.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_PI_InspectorNotes	CoA for an API used
Doc02_PI_InspectorNotes	List of drugs and sample labels of white bagged drugs dispensed.
Doc03_GP82.00	REMS programs used
Doc04_HZ1.02	Antineoplastic agents requiring manipulation
Doc05_HZ2.02	HDs handled in compliance with complete requirements of USP <800>

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	X
Open to the Public		Nuclear Pharmacy	
Closed Door	X	Specialty Pharmacy	X
Drive-through window		White bagging/ clear bagging	X
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)	X	Wholesale Distributor	X
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	X
Internet Pharmacy		Sterile Hazardous Drug Compounding	X

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	X
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	X
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	X
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	X
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	X
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	21211	Total Pharmacists:	26
Nonsterile Compounding Room size:	N/A	Number of Compounding Pharmacists:	24
Nonsterile Compounding powder hoods number:	N/A	Total Student Interns:	6
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Technicians:	30
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	N/A	Number of Compounding Technicians:	27
Sterile Compounding Ante Room size:	226	Of technicians, how many are nationally certified?	6
Sterile Compounding Clean/Buffer Room size:	2196	Of technicians, how many are techs-in-training?	4
Sterile Compounding Number LAFW hoods/areas:	17/15 each	Total Other Unlicensed Personnel:	13 RNs
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	~1:1
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	398		
Sterile HD Compounding Number of BSC hoods:	5		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	Compounding was observed through three viewing windows located directly behind the compounder.

	Volume Dispensed		**Volume Distributed**
Total Prescriptions Dispensed/day:	840	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	<0.1%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	18%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	17%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)	0	0	April 2024
Arizona (AZ)	22	0	April 2024
Arkansas (AR)			
California (CA)			
Colorado (CO)	21	0	April 2024
Connecticut (CT)	7	0	April 2024
Delaware (DE)	175	0	April 2024
District of Columbia (DC)			
Florida (FL)	231	0	April 2024
Georgia (GA)	99	0	April 2024
Hawaii (HI)	0	0	April 2024
Idaho (ID)	0	0	April 2024
Illinois (IL)	17	0	April 2024
Indiana (IN)	91	0	April 2024
Iowa (IA)	2	0	April 2024
Kansas (KS)			
Kentucky (KY)	25	0	April 2024
Louisiana (LA)	0	0	April 2024
Maine (ME)	0	0	April 2024
Maryland (MD)	380	0	April 2024
Massachusetts (MA)			
Michigan (MI)	0	0	April 2024
Minnesota (MN)	0	0	April 2024
Mississippi (MS)	6	0	April 2024
Missouri (MO)	9	0	April 2024
Montana (MT)	0	0	April 2024

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	0	0	April 2024
Nevada (NV)			
New Hampshire (NH)	8	0	April 2024
New Jersey (NJ)	74	0	April 2024
New Mexico (NM)	0	0	April 2024
New York (NY)	295	0	April 2024
North Carolina (NC)	10	0	April 2024
North Dakota (ND)	0	0	April 2024
Ohio (OH)	596	0	April 2024
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)	111,673	0	April 2024
Rhode Island (RI)	0	0	April 2024
South Carolina (SC)	70	0	April 2024
South Dakota (SD)	0	0	April 2024
Tennessee (TN)	23	0	April 2024
Texas (TX)			
Utah (UT)	3	0	April 2024
Vermont (VT)	0	0	April 2024
Virginia (VA)	37	0	April 2024
Washington (WA)	0	0	April 2024
West Virginia (WV)	707	0	April 2024
Wisconsin (WI)	10	0	April 2024
Wyoming (WY)	0	0	April 2024
Other:			

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General Pharmacy Inspection

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Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania
e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	No	Jessica Norris, Lead Pharmacist was on duty. This inspector spoke to the PIC by phone prior to the precall. The PIC was not available to participate in the precall or the onsite inspection.
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	The PIC is on site 40 to 50 hours per week.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	Yes	CarepathRx LLC is a the same address. CarepathRx is a managed service organization that performs data entry and prescription processing. The University of Pittsburg Medical Center (UPMC) owns a 40% stake of CarepathRx, LLC.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		The PIC was not present. Staff interviewed included Jessica Norris, Lead Pharmacist; Marissa Davis, Supervisor of Pharmacy Operations; David Benedict, Chief Operations Officer; Lori Tinlin, Manager of Accreditation; and Megan Zielke, Medication Safety Pharmacist.

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Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania
e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Of the delivered prescriptions to a provider for administration, <1% are delivered in West Virginia and approximately 10% are delivered in Pennsylvania.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania
e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	N/A	This is a closed-door facility, however, all licenses are posted in the main hallway near the pharmacy.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The last inspection by the Pennsylvania Board of Pharmacy was dated 3/28/2024. The board of pharmacy inspects annually.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	Yes	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	

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Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania
e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	The pharmacy is accredited by NABP for Compounding Pharmacy from a survey dated 4/25/2023; URAC accredited the pharmacy for Specialty Pharmacy from a survey dated 6/10/2021; ACHC accredited the pharmacy for Infusion Pharmacy dated 10/10/2022; ACHC accredited the pharmacy for PCAB from a survey dated 10/10/2022.
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? ***Verify that the lab director is current (usually the PIC is the lab director named).*** *If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	This is a closed-door pharmacy.
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are maintained for 10 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	They are maintained electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	They are maintained electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	They are maintained electronically.

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e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is a part of P & P.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	All licenses are provided to UPMC Human Resources and recorded upon hire. The PIC also maintains a record of licensing via a spreadsheet.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	UPMC HR reviews primary source verification for all licenses every month.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	There is no technician ratio requirement in PA. The maximum working at any given time would be 14 technicians and 14 pharmacists in the processing area.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The security system is managed by Convirgent Technologies LLC and monitored by UPMC. There are motion detection devices throughout the building and magnetic door sensors on all doors. The main entrance is locked at all times. There are panic alarms throughout the building. All restricted areas are electronic badge accessed. Alarms are sent to the local police, the PIC, and a phone tree.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	CII drugs are in an Omnicell cabinet, which is login based. Only pharmacists have a unique login code.

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Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania
e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	A pharmacist would remain onsite until UPMC security arrives to ensure security.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No destruction onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Inmar.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Stericycle and Veolia manage hazardous waste and pick up monthly.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	This is a closed door pharmacy.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The HVAC system is set with a range of 70 to 72 degrees F and is systematically maintained in that range. The system is not thermostatically controlled. The current temperature is 69.5 degrees F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Automated Logic is the continuous monitoring and recording system used for all temperature monitoring. Records are maintained infinitely. Excursions are sent to the PIC and a call list by phone call.

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e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	Drugs would be quarantined and professional literature reviewed to determine drug integrity. The manufacturer may be contacted for stability studies if necessary.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Automated Logic is the continuous monitoring and recording system used for all temperature monitoring. Records are maintained infinitely. Excursions are sent to the PIC and a call list by phone call. The temperature range is 2 to 6 degrees C.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	There are 14 refrigerators with temperatures ranging from 37.7 to 41.6 degrees F.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	There are no drugs requiring frozen storage.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	There are no drugs requiring frozen storage.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	There is an onsite generator which operates the entire facility. There are multiple refrigerators allowing products to be relocated to a working appliance if necessary.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	There is redundant HVAC, with four systems that can manage HVAC for the entire facility should one unit become inoperable.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	The pharmacy would reach out to manufacturers for stability studies.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	There are two Omnicell IV stations, one Baxter EM2400 TPN Compounder, and five repeater pumps.
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	

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General Pharmacy Inspection

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e-Profile ID: 802348
Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The UPMC Supply Chain Management department handles the process of vendor selection and management.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	Yes	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Cardinal Health is the primary wholesaler. McKesson, HC Pharmacy Wholesaler (GPO-group purchasing organization), Anda, and Hercules Rx are also used per the Lead Pharmacist. All suppliers are NABP-accredited wholesalers other than HC Pharmacy which is a UPMC developed wholesale group that is required to purchase only from manufacturers or wholesalers such as Cardinal, who must purchase directly from the manufacturer. HC Pharmacy was discontinued, per David Benedict, COO, during this inspection.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	The UPMC Supply Chain Management department requires all wholesaler purchases to be made directly from the manufacturer.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	The UPMC Supply Chain Management performs this process.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	The UPMC Supply Chain Management performs this process.

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		Observation	Notes
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	Drugs are quarantined and reported to UPMC Supply Chain Management for investigation.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	The product is quarantined and the UPMC Supply Chain Management team and the WD are contacted.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	The PIC, the Lead Pharmacist, and the Supervisor of Pharmacy Operations have Power of Attorney for signing a DEA Form 222.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	

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		Observation	Notes
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	An electronic perpetual inventory is part of the order processing system.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	UPMC Security, the local police, and the DEA may be notified if appropriate.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	The Omnicell maintains a perpetual inventory of all CII drugs. The inventory is reconciled weekly, and monthly.
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	The inventory is reconciled weekly, and monthly.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	The complete controlled substance inventory is performed monthly, and every two years for the DEA. The last biennial inventory was dated 4/28/2023.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	

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		Observation	Notes
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs.* *If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs.* *If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Stock is reviewed monthly and is pulled from saleable stock 2 months in advance in specialty and 30 to 60 days in advance in the rest of the pharmacy.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Stock is reviewed monthly.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	N/A	This is a closed-door pharmacy.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

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		Observation	Notes
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	CarepathRx Patient Pharmacy Associates (PPA) create patient profiles that are updated with each patient encounter.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	Due to the nature of the business model, all prescribers are known and confirmed. Fraudulent prescriptions are unlikely. Staff is trained for and is familiar with fraud detection.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Fraud would be reported by contacting the prescriber and would also be reported to the Board of Pharmacy and the DEA if applicable.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Due to the nature of the business model, medications dispensed are infusion and specialty medications with established patient-prescriber relationships, from the UPMC facilities.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Capability is for noncontrolled and controlled substances.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	A minimum of two pharmacists review entered data during the onboarding process and with each prescription.

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		Observation	Notes
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR occurs during the clinical pharmacist review and before a prescription label is generated.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	There is access to physician notes, lab values, and testing performed at the hospital/clinic.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Reporting is electronic and daily.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	Data is accessed when appropriate.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Overrides are performed only by a pharmacist. Documentation is systematically recorded using the pharmacist's logon credentials.

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		Observation	Notes
67.07	Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	Yes	Medispan is the integrated drug database used for DUR.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Filled prescriptions are verified using bar code scanning during the compounding process for compounded prescriptions, and also used for specialty prescriptions. Filled prescriptions are also visually reviewed by the pharmacist using the filled product and the scanned electronic prescription.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Specialty pharmacy uses the CPR+ system. Infusion pharmacy uses the HomecareNet 360 system.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	Yes	Data entry, DUR, and adjudication are performed in the same building by CarepathRx through a contractual agreement.

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72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	Yes	CarepathRx is partially commonly owned and operates under a contractual agreement with Chartwell, under Pennsylvania Board of Pharmacy license # PP483012.
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	No	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	Yes	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	There are no prescriptions picked up at this closed door pharmacy.
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	There are no prescriptions picked up at this closed door pharmacy.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	There are no prescriptions picked up at this closed door pharmacy.

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76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	There are no prescriptions picked up at this closed door pharmacy.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	There are no prescriptions picked up at this closed door pharmacy.
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	There are no prescriptions picked up at this closed door pharmacy.
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	A patient welcome handbook is provided to each new patient with a toll-free number listed for counseling. Printed material containing the toll-free number is systematically printed and provided to each patient with each prescription. A pharmacist also speaks to each patient prior to delivery.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	A patient welcome handbook is provided to each new patient with a toll-free number listed for counseling. Printed material containing the toll-free number is systematically printed and provided to each patient with each prescription. A pharmacist also speaks to each patient prior to delivery.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	PPIs are systematically printed and provided when required.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	MedGuides are systematically printed and provided when required.

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		Observation	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	Yes	Please see Doc03_GP82.00 for the list of REMS drugs dispensed.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	All documentation related to counseling is stored in the pharmacy system in the patient notes section.
84.00	Do patients have 24-hour access to a pharmacist? ***Note: may not be required by the resident state.*** *Describe how (such as posted contact information and hours of operation).*	Yes	The toll-free number is in the patient welcome packet and on all written communication to the patient.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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		Observation	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	The CQI program is overseen by Jennifer Ashner, RN, Director of Compliance.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	P & P is electronic.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Documentation for actual errors is electronic, using RiskMaster, a UPMC system. Near-misses are recorded in an electronic internal near-miss log. Both the RiskMaster records and the near-miss logs are sent electronically to the CQI team.

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		Observation	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	The CQI team analyzes all data submitted with each event monthly, with meetings with personnel to review observed issues.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	There is no drug formulary used.
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Meetings are monthly.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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National Association of Boards of Pharmacy®
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General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Events are reported to ISMP.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	Reports are made to the boards of pharmacy if appropriate.
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	Consumer surveys are sent at the end of therapy for a patient, or patients are randomly selected. Surveys may be sent electronically or mailed.
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Sterile Compounding Inspection for USP <797>

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		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		**Please note NABP did not review each SOP for alignment on USP <797>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***	Yes		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18

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		Observation	Inspector Notes	USP Reference(s)
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17

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		Observation	Inspector Notes	USP Reference(s)
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		17

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		Observation	Inspector Notes	USP Reference(s)
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		PH104 Aseptic Compounding Considerations	1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		PH104 Aseptic Compounding Considerations	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		PH104 Aseptic Compounding Considerations; Hand Hygiene and Garbing Attachment 3	3, 3.3

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		Observation	Inspector Notes	USP Reference(s)
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		PH202 Surface and Air Testing of Primary and Secondary Engineering Controls; PH300 Routine and Preventive Management for Primary Engineering Controls; PH3012 Routine and Preventive Maintenance for Secondary Engineering Controls	4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		PH202 Surface and Air Testing of Primary and Secondary Engineering Controls	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		PH202 Surface and Air Testing of Primary and Secondary Engineering Controls; Attachment 2	
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		PH110 Cleaning and Disinfecting of the Compounding Area	7, 7.2 Box 7, Box 8

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		Observation	Inspector Notes	USP Reference(s)
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		PH302 Routine Maintenance of Compounding Equipment	9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		PH001 Drugs and Product Selection; PH002 Purchasing Drugs and Supplies; PH003 Purchasing Controlled Substances; PH004 Storage and Security of Drugs and Products	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		PH101 Master Formulations and Compounding Records	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		PH109 Guidelines for Dispensing Products and Equipment	12, 18, 20
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.		PH102 Drug Labeling	13

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		Observation	Inspector Notes	USP Reference(s)
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		OPS056 Shipping and Cold Chain Management	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		PCR002 Documentation Requirements for Pharmacy Only Patients	20
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		PH108 Category 2 Compounding from Nonsterile Ingredients	10
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.3

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		Observation	Inspector Notes	USP Reference(s)
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***	[redacted]	N/A	1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***	[redacted]	N/A	21
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A	There are no compounds for direct and immediate use.	1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3

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4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3

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5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	Yes		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	Yes		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	Yes		1.4

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6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	Yes		1.4
6.1	The product is prepared as a single dose for an individual patient.	Yes		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	Yes		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	No		1.1.2

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		Observation	Inspector Notes	USP Reference(s)
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2
	Facility Design and Engineering Controls			4
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5

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9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops)*** .	N/A		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	N/A		4.2.1, 4.3.2

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		Observation	Inspector Notes	USP Reference(s)
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	Yes		4.2.1
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes		4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2

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		Observation	Inspector Notes	USP Reference(s)
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3
13.5	**Category 2 and Category 3**: PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	No		4.2.3 Table 5

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		Observation	Inspector Notes	USP Reference(s)
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes	Sterile 70% IPA is used.	4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5

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		Observation	Inspector Notes	USP Reference(s)
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	N/A		4.4

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		Observation	Inspector Notes	USP Reference(s)
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	Yes		4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	This is prevented by interlock.	4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	This is prevented by interlock.	4.2.1

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		Observation	Inspector Notes	USP Reference(s)
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected. If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	N/A	Carts are dedicated and not moved from their designated area.	4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	N/A	Carts are dedicated and not moved from their designated area.	4.5

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		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	A continuous recording and monitoring system is used.	4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes	A continuous recording and monitoring system is used.	4.2, 9.3.4, 19.1
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes	A continuous recording and monitoring system is used.	4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes	A continuous recording and monitoring system is used.	4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	Monitoring devices are verified for accuracy every month and sensors are replaced as required.	4.2, 9.3.4

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		Observation	Inspector Notes	USP Reference(s)
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	Monitoring devices are verified for accuracy every month and sensors are replaced as required.	4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	No	Only TPN ingredients are stored in the cleanroom.	4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	N/A		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	[redacted]	The cleanroom suite temperatures are as follows: TPN- 64.7 degrees F; Antibiotic- 62.2 degrees F; Hazardous 63.6 degrees F; Hazardous anteroom- 66.1 degrees F; Non-hazardous anteroom- 64.8 degrees F; High-risk area- 68.5 degrees F.	4.2, 9.3.4, 19.1

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Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

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		Observation	Inspector Notes	USP Reference(s)
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***	[redacted]	The cleanroom suite humidities are as follows: TPN- 48.9%; Antibiotic- 52.8%; Hazardous- 48.8%; Hazardous anteroom- 44.5%; Non-hazardous anteroom- 49.6%; High-risk area- 42.1%.	4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	Yes	The alert is a visual alert on the device panel at the doors to the suite.	4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	No		4.2.1
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	N/A		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6

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		Observation	Inspector Notes	USP Reference(s)
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	N/A		4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	N/A		4.2.1
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.6

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		Observation	Inspector Notes	USP Reference(s)
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	Yes		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	Yes		4.2.6
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes		5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20

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		Observation	Inspector Notes	USP Reference(s)
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes	The certification report is stamped "Received" and initialed by the PIC. While the appearance indicates the report is "received, and not "reviewed", staff stated the PIC reviews the report. Numerous pages are initialed providing evidence of a review.	4.2, 5

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		Observation	Inspector Notes	USP Reference(s)
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes		5, 20

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		Observation	Inspector Notes	USP Reference(s)
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20

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		Observation	Inspector Notes	USP Reference(s)
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	N/A		4.2.4, 5 Table 6
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6

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		Observation	Inspector Notes	USP Reference(s)
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5

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		Observation	Inspector Notes	USP Reference(s)
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes	The smoke pattern test was documented with a video.	4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1

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		Observation	Inspector Notes	USP Reference(s)
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A	There were no leaks identified.	5

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		Observation	Inspector Notes	USP Reference(s)
33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	N/A		4.2.3
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3

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34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	N/A		5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes		6, 6.1, 6.2
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2

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35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes		6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20

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		Observation	Inspector Notes	USP Reference(s)
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes		6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes		6.3

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		Observation	Inspector Notes	USP Reference(s)
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab. If no, describe observations.***	Yes		6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to compliance statements.***	Yes		6.3
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1

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		Observation	Inspector Notes	USP Reference(s)
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes		6.3, 6.3.1, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8

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		Observation	Inspector Notes	USP Reference(s)
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1

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42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes		3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	Yes	There are no accommodations made.	3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	No		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	Yes		3.3
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A	Only disposable garb is used.	3.3
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3

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44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes		2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	N/A		Box 2
	Cleaning and Disinfection			7
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used within PEC).	Yes		7.1.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes	Reusable tools (handles and heads) are all stainless steel.	7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes		7.1.1 Box 7 <1072>

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		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.*** ***Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	Yes	The sporicidals used are RTU sterile TB1-3300 and Peridox.	7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. ***If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.***	N/A		7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
	Components			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3

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		Observation	Inspector Notes	USP Reference(s)
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes		9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	Yes		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes." If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3

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51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Supplies			9
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1

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52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4

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53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes		9.1
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2

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53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	A continuous electronic monitoring and recording device is used.	6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1

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Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	There are no accommodations permitted.	3.1
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3

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		Observation	Inspector Notes	USP Reference(s)
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3

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		Observation	Inspector Notes	USP Reference(s)
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	No		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	No	This inspector observed a small amount of hair protruding from the compounder's bonnet. The observation was drawn to the attention of Jessica Norris, Lead Pharmacist.	3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3

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Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #97.***	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately. If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	Yes		3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing). If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Compounding of Ampicillin-Sulbactam 3 GM/100 ml 0.9% NaCl in EZ pumps was observed.	
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2

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		Observation	Inspector Notes	USP Reference(s)
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes	Sterile 70% IPA is used.	8.1

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		Observation	Inspector Notes	USP Reference(s)
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3

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		Observation	Inspector Notes	USP Reference(s)
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.***	Yes		15

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		Observation	Inspector Notes	USP Reference(s)
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1

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		Observation	Inspector Notes	USP Reference(s)
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	N/A		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates).*** ***These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes		7

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Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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		Observatio	Notes
81.00	Areas, other than the work surface of the C PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	Yes	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	There have been no spills at this location.

Pharmacy Name:	Chartwell Pennsylvania, LP
Pharmacy Address:	1001 Oakdale Road, Oakdale, PA 15071
NABP Business e-Profile ID:	802348
VPP Inspection Date(s):	5/20/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	91	43.3	The pharmacy does stock head coverings (e.g., Medline Bouffant Caps (lightweight polypropylene material) - Item #:CRI1004) that are low lint and, when worn properly as trained, cover the hair and ears.	N/A	N	
Other	117	56.0 & 56.2	Small amount of hair protruded from a one compounder's head covering. To ensure hair cannot protrude from head coverings, the pharmacy is converting all head coverings warn in our cleanrooms to full-head coverings (e.g., ULINE Hair & Beard Net Combo (lightweight polypropylene material) - Item #: S-21130W), which provide coverage of the user's entire head and the majority of thier neck.	7/11/2024	N	
Clarification or Further Explanation	170	86.0	The pharmacy's documented training program and ongoing competency evaluation is compliant with USP <797> standards. Applicable employee files were secured in PIC's office, and were unavailable due to extenuating circumstances that prevented the PIC from being present to provide.	N/A	N	
Clarification or Further Explanation	171	86.0 (2.1-#1)	Employee Record #1: Pharmacist (B. Plant; Hire Date: 10/17/2022), Supervising/Direct Oversight, Category 2 only. Initial & On-going training documenting knowledge & competency of core skills. Training processes and documentation have continued to evolve since 2021 when PIC changed.	N/A	Y	Attachment 1.a-Orientation_CWP Checklist & Documents_Plant, Bryce_20221201 Attachment 1.b.-Attestation_PH110 Policy Review (2022)_Plant, Bryce_20221201 Attachment 1.c.-Competency_OJT TPN Compounder (Pinnacle)_Initial_Plant, Bryce_20221228 Attachment 1.d.-Orientation_OJT Infusion Checklist_Plant, Bryce_20230118 Attachment 1.e.-Initial_CriticalPoint Sterile Compounding_Plant, Bryce_20221019 Attachment 1.f.-Ongoing_CriticalPoint Sterile Compounding_Plant, Bryce_20231230 Attachment 1.g.-Competency_OJT Repeater Pump_Initial_Plant, Bryce_20230104 Attachment 1.h.-Attestation_PH110 Policy Review (2023)_Plant, Bryce_20240117 Attachment 1.i.-Competency_OJT Cleaning & Disinfection_2023_Plant, Bryce_20240117 Attachment 1.j.-Competency_OJT TPN Compounder (EM2400)_Initial_Plant, Bryce_20240201 Attachment 1.k.-Competency_OJT Repeater Pump (Baxter)_Initial_Plant, Bryce_20240502 Attachment 1.l.-Competency_Assessment Repeater Pump (Baxter)_Initial_Plant, Bryce_20240502
Clarification or Further Explanation	172	86.0 (2.1-#2)	Employee Record #2: Pharmacist (A. Morningstar; Hire Date: 11/22/2021), Supervising/Direct Oversight, Category 2 only. Initial & On-going training documenting knowledge & competency of core skills.	N/A	Y	Attachment 2.a.-Orientation_CWP Checklist & Documents_Morningstar, Amberly_20211201 Attachment 2.b.-Attestation_PH110 Policy Review (2022)_Morningstar, Amberly_20221013 Attachment 2.c.-Competency_OJT TPN Compounder (Pinnacle)_Ongoing_Morningstar, Amberly_20220921 Attachment 2.d.-Orientation_OJT Infusion Checklist_Morningstar, Amberly_20220921 Attachment 2.e.-Initial_CriticalPoint Sterile Compounding_Morningstar, Amberly_20211209 Attachment 2.f.-Ongoing_CriticalPoint Sterile Compounding_Morningstar, Amberly_20221210 Attachment 2.g.-Ongoing_CriticalPoint Sterile Compounding_Morningstar, Amberly_20230622 Attachment 2.h.-Attestation_PH110 Policy Review (2023)_Morningstar, Amberly_20240110 Attachment 2.i.-Competency_OJT Cleaning & Disinfection_2023_Morningstar, Amberly_20240110 Attachment 2.j.-Competency_OJT TPN Compounder (EM2400)_Initial_Morningstar, Amberly_20240202 Attachment 2.k.-Competency_OJT Repeater Pump (Baxter)_Initial_Morningstar, Amberly_20240503 Attachment 2.l.-Competency_Assessment Repeater Pump (Baxter)_Initial_Morningstar, Amberly_20240503
Clarification or Further Explanation	172	86.0 (2.1-#3)	Employee Record #3: Pharmacist (R. Robb; Hire Date: 3/4/2024 - Actively in Orientation Phase), Supervising/Direct Oversight, Category 2 only. Initial & On-going training documenting knowledge & competency of core skills.	N/A	Y	Attachment 3.a.-Orientation_CWP Checklist & Documents_Robb, Rachel_20240528 Attachment 3.b.-Attestation_PH110 Policy Review (2023)_Robb, Rachel_20240418 Attachment 3.c.-Initial_CriticalPoint Sterile Compounding_Robb, Rachel_20240308 Attachment 3.d.-Competency_OJT Cleaning & Disinfection_2023_Robb, Rachel_20240418 Attachment 3.e.-Competency_OJT Repeater Pump (Baxter)_Initial_Robb, Rachel_20240502 Attachment 3.f.-Competency_Assessment Repeater Pump (Baxter)_Initial_Robb, Rachel_20240502

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name:	Chartwell Pennsylvania, LP
Pharmacy Address:	1001 Oakdale Road, Oakdale, PA 15071
NABP Business e-Profile ID:	802348
VPP Inspection Date(s):	5/20/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	172	86.0 (2.1-#4)	Employee Record #4: Pharmacy Technician (E. Daluisio; Hire Date: 9/12/2022), Compounder, Category 2 only. Initial & On-going training documenting knowledge & competency of core skills.	N/A	Y	Attachment 4.a.-Orientation_CWP Checklist & Documents_Daluisio, Eligio_20220922 Attachment 4.b.-Attestation_PH110 Policy Review (2022)_Daluisio, Eligio_20221017 Attachment 4.c.-Inital_CriticalPoint Sterile Compounding_Daluisio, Eligio_20220914 Attachment 4.d.-Orientation_OJT Infusion Checklist_Daluisio, Eligio_20221207 Attachment 4.e.-Competency_OJT Repeater Pump_Initial_Daluisio, Eligio_20221221 Attachment 4.f.-Competency_OJT TPN Compounder (Pinnacle)_Initial_Daluisio, Eligio_20221221 Attachment 4.g.-Ongoing_CriticalPoint Sterile Compounding_Daluisio, Eligio_20231105 Attachment 4.h.-Attestation_PH110 Policy Review (2023)_Daluisio, Eligio_20240123 Attachment 4.i.-Competency_OJT Cleaning & Disinfection_2023_Daluisio, Eligio_20240123 Attachment 4.j.-Competency_OJT TPN Compounder (EM2400)_Initial_Daluisio, Eligio_20240411 Attachment 4.k.-Competency_OJT Repeater Pump (Baxter)_Initial_Daluisio, Eligio_20240502 Attachment 4.l.-Competency_Assessment Repeater Pump (Baxter)_Initial_Daluisio, Eligio_20240502
Clarification or Further Explanation	172	86.0 (2.1-#5)	Employee Record #5: Pharmacy Technician (Z. Chandler; Hire Date: 2/19/2024 - Actively in Orientation Phase), Compounder, Category 2 only. Initial & On-going training documenting knowledge & competency of core skills.	N/A	Y	Attachment 5.a.-Orientation_CWP Checklist & Documents_Chandler, Zion_20240418 Attachment 5.b.-Initial_CriticalPoint Sterile Compounding_Chandler, Zion_20240229 Attachment 5.c.-Attestation_PH110 Policy Review (2023)_Chandler, Zion_20240418 Attachment 5.d.-Competency_OJT Cleaning & Disinfection_2023_Chandler, Zion_20240418 Attachment 5.e.-Orientation_OJT Infusion Checklist_Chandler, Zion_20240701 Attachment 5.f.-Competency_OJT TPN Compounder (EM2400)_Initial_Chandler, Zion_20240417 Attachment 5.g.-Competency_OJT Repeater Pump (Baxter)_Initial_Chandler, Zion_20240502 Attachment 5.h.-Competency_Assessment Repeater Pump (Baxter)_Initial_Chandler, Zion_20240502

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

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Hazardous Drugs Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
	Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)		
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C PEC and the solution used does not alter the product label.	Yes	

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		Observatio	Notes
	Dispensing, Packaging, and Compounding Processes		
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	Yes	
75.00	Clean, dedicated (not used for non HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	**Recommendation**: Equipment is decontaminated after every use.	Yes	
75.02	**Recommendation**: When compounding, a plastic backed preparation mat is placed on the C PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	Yes	
75.02.01	Immediately if a spill occurs	Yes	
75.02.02	Regularly during use	Yes	
75.02.03	At the end of a shift	Yes	
76.00	APIs or other powdered HDs are handled in a C PEC during particle generating activities, such as crushing, opening capsules, and weighing powders.	N/A	There are no hazardous APIs or other powdered HDs.

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		Observatio	Notes
	Labeling, Packaging, Transport, and Disposal		
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	Yes	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in SDS for transport;	Yes	
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C PEC.\	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. *List last date of damaged package receipt.*	Yes	There have been no damaged HD packages received.

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
	Environmental Quality and Control - Surface wipe sampling		
62.00	**Recommendation**: **Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	No	
62.01	Interior of C-PEC and equipment within the C-PEC	No	
62.02	Pass-through chambers	No	
62.03	Surfaces in staging or work areas near the C-PEC	No	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	No	
62.05	Areas immediately outside the HD buffer room or the C-SCA	No	
	Receiving		
63.00	**Recommendation**: HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Yes	
65.00	A spill kit is readily accessible in the receiving area.	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	N/A	
61.00	If the negative pressure HD buffer room is entered through a positive pressure non HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	N/A	
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	Yes	
61.02	Indicate how HD contamination is minimized:		
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	Yes	
61.02.02	Use of sealed containers	Yes	
61.02.03	Other, *describe*	Yes	All product is double wrapped and bagged when transported

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
59.02	A handwashing sink is at least one meter or more away from the C-PEC	Yes	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		The sink is outside the C-SCA.
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	N/A	There are no Category 1 preparations.
60.01	The buffer room has fixed walls.	N/A	
60.02	The buffer room is externally vented.	N/A	
60.03	The buffer room has HEPA filtered supply air.	N/A	
60.04	The buffer room has at least 30 ACPH.	N/A	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	N/A	
60.06	The anteroom has fixed walls.	N/A	
60.07	The ante room has a minimum of 30 ACPH of HEPA filtered supply air.	N/A	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	N/A	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
55.01.07	LAFW (not for antineoplastics)	No	
55.01.08	CAI (not for antineoplastics)	No	
56.00	The C PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	Yes	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	Yes	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non HD preparations, is the non HD preparation placed into a protective outer wrapper during removal from the C PEC?	N/A	
58.01	If used for both, is the non HD preparation labeled to require PPE handling precautions?	N/A	
59.00	If the C SEC is an unclassified containment segregated HD compounding area (C SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
52.03	Is the C PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C SEC has at least 12 ACPH. *Verify documentation and monitoring.*	N/A	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non shedding. *If non-compliant describe.*	N/A	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01 61.02.03. If no, skip to 62.	Yes	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding**:		
55.01.01	CACI	No	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	No	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	Yes	
55.01.04	Class II BSC, Type B1	No	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	No	
55.01.06	Class III BSC	No	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding**:		
50.02.01	Class I biological safety cabinet (BSC)	N/A	
50.02.02	Class II BSC	N/A	
50.02.03	Containment ventilated enclosure (CVE)	N/A	
50.02.04	Compounding aseptic containment isolator (CACI)	N/A	
50.02.05	Other, describe	N/A	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; **and/or**	N/A	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	N/A	
52.00	Does the pharmacy use the same C PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	N/A	
52.01	Is **nonsterile HD compounding** only "occasional"? / *If yes, please describe frequency and quantity.*	N/A	
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	N/A	

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		Observatio	Notes
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C PEC operates continuously if it supplies some or all of the negative pressure in the C SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water sources and drains are a minimum of 1 meter away from the C PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01 54. If no, skip to 55:	No	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	N/A	
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N/A	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C SCA]).	Yes	
44.04	**Recommendation**: *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	N/A	
45.00	If non antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non HD inventory, there is a written policy/SOP addressing it.	N/A	
46.00	**Compounding**: There are appropriate engineering controls to protect the HD preparation from cross contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C PEC located in a C-SEC room.	Yes	
47.01	The C SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C SEC).	Yes	
43.00	**Storage**: Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	HD drugs are stored in a restricted negative pressure room.
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	N/A	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non HDs.	Yes	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Yes	

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Hazardous Drugs Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	N/A	There is no non-sterile compounding.
39.04	Sterile HD compounding (if performed by the pharmacy)	Yes	
40.00	***Recommendation*** *: If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	Yes	
41.00	**Receipt**: Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	The area is a designated space near the dock, which has a fume hood in a negative pressure room.
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Yes	The area is a designated space near the dock, which has a fume hood in a negative pressure room.
41.01.01	Neutral	No	
41.01.02	Negative	Yes	

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		Observatio	Notes
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C PEC or contained in a sealable bag for discarding outside the C PEC.	Yes	
	Facilities and Engineering Controls		
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	

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		Observatio	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	N95 respirators and PAPR are available. Equipment is fit-tested when required.
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
35.03	Full-facepiece, chemical cartridge-type respirator;	No	
35.04	PAPR; and/or	Yes	
35.05	Other (describe in notes).	N/A	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE**: Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
33.00	**Respiratory Protection**: The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit tested, when required).*	Yes	N-95 masks, N95 respirators, and PAPR are available. Equipment is fit-tested when required.
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	These are available for drivers.
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
33.03	Full-face piece, chemical cartridge-type respirator;	No	
33.04	PAPR; and/or	Yes	These are available for the spill team.
33.05	Other (describe in notes).	N/A	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	

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		Observatio	Notes
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C SEC and doffed when exiting the C SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection**: The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C PEC), if required.	Yes	
32.01	If a risk to eyes, goggles (or a full face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Yes	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full face respirator) are worn.	N/A	

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		Observatio	Notes
30.00	**Gowns**: The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	

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		Observatio	Notes
29.00	**Gloves**: The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation**: Are *chemotherapy gloves worn for handling all HDs including non antineoplastics and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	Yes	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation**: Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	Yes	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	

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		Observatio	Notes
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	N/A	There is no non-sterile compounding.
26.05	Sterile Compounding (if performed by the pharmacy);	Yes	
26.06	Administration, if applicable;	N/A	There is no administration at this facility.
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	There is no administration at this facility.
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	Yes	All PPE is disposable other than goggles, which are cleaned and decontaminated as required.

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	Yes	
	Personal Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	

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		Observatio	Notes
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	Yes	
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	

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		Observatio	Notes
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	
	Personnel Training --*Check four employee files for documentation*		
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	
18.00	For non sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	N/A	There is no non-sterile compounding.

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		Observatio	Notes
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	Yes	
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	

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		Observatio	Notes
13.19	Administering SOPs, if applicable	N/A	There is no administration.
13.20	***Recommendation: Environmental monitoring (eg, wipe sampling) SOPs***	N/A	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	N/A	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
13.22.01	Size and scope of spill;	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits;	Yes	
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	

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		Observatio	Notes
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Yes	The container is moved to the fume hood in the receiving area.
13.14.03	container is placed on a plastic-backed preparation mat;	Yes	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	The receiving fume hood is cleaned and decontaminated. The HD does not go into the sterile compounding PEC.
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	N/A	The receiving fume hood is used.
13.15	Safe work Practices SOPs	N/A	
13.16	Dispensing SOPs	N/A	
13.17	Packaging and labeling SOPs	N/A	
13.18	Transport SOPs	N/A	

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		Observatio	Notes
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Yes	
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and **does not need to be opened**:		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	
13.14	If a damaged shipping container **must be opened**:		
13.14.01	Container is sealed in plastic or an impervious container;	Yes	

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Hazardous Drugs Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs Handling in Health Care Settings Inspection is based on USP Chapter <800>.

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C PECs], containment secondary engineering control [C SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents used	Yes	
13.11.02	Dilutions, if used	N/A	All agents are RTU.
13.11.03	Frequency	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
13.00	SOPs address at a minimum: *If no, document "missing" in Inspector Notes for each SOP topic*		**Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**
13.01	Hazard communication program plan	Yes	
13.02	Competent personnel	Yes	
13.03	Occupational safety program	Yes	
13.04	Designation of HD areas	Yes	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	
13.06	A list of HDs	Yes	
13.07	Storage of HDs	Yes	
13.08	Compounding of HDs	Yes	

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e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
10.02	**Dispensing**: Counting or packaging tablets and capsules	Yes	
10.03	**Compounding/other manipulations**: Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	
10.04	**Administration and other patient care activities** (if applicable).	N/A	There is no administration or patient care activities.
10.05	**Spills**: Spill generation, management, and disposal.	Yes	
10.06	**Transport**	Yes	
10.07	**Waste**: Collection and disposal of HD waste and trace contaminated waste	Yes	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	SOPs are electronic and can be printed as necessary.

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e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	Yes	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	Yes	The latest assessment of risk was dated 2/13/2024.
	Personnel Responsibilities		
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	
	Documentation and Standard Operating Procedures (SOPs)		
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		
10.01	**Receiving**: Contacting HD residues on packaging, work surfaces, floors	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	Yes	
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	Yes	
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	Yes	
8.02	Dosage form;	Yes	
8.03	Risk of exposure;	Yes	
8.04	Packaging;	Yes	
8.05	Manipulation; and	Yes	

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Inspection Date: 05/20/2024 - 05/21/2024

		Observatio	Notes
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	Yes	Please Doc05_HZ2.02.
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	N/A	
	List of Hazardous Drugs		
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Yes	There are two hazardous lists, one for Specialty and one for Infusion. The lists are reviewed annually and each time a new drug is added. The Infusion list was reviewed 12/2023. The Specialty list was reviewed 5/2024.
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	

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		Observatio	Notes
	General Information and Scope:		
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	Yes	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	N/A	
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	Yes	Please see Doc04_HZ1.02.
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	Yes	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	Yes	The single drug handled without further manipulation other than counting and packaging is fluconazole.

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GLOSSARY USP <797>
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Sterility assurance level (SAL): See the entry for *Probability of a nonsterile unit* (PNSU).
Sterility: The absence of viable microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.
Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-µm pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

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GLOSSARY USP <797>
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

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GLOSSARY USP <797>
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package.*
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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GLOSSARY USP <797>
ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.

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GLOSSARY USP <797>
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance.*
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.

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GLOSSARY USP <797>
Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions).* This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study).*
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

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GLOSSARY USP <797>
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class)*.
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

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GLOSSARY USP <797>
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient.*
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

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GLOSSARY USP <797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).

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#3	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	N/A	There were no failures observed.
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	There were no failures observed.
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	There were no failures observed.
#6									
#7									
#8									
#9									
#10									

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Inspector Instructions	Aseptic Manipulation Competency (Section 2.3)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. **2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.** **3. Select the appropriate response for each item reviewed.** **-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.** **-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.** **-Select "Missing" if the document is not present in the file.** **-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.** **4. Use the notes column to document any pertinent information.** **5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).**	**USP requirements:** **1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel.** **2. The pharmacy conducts media-fill testing as described in Box 2.** **3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band.** **4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.** **5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands.** **6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device.** **7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency.** **8. Documentation includes, at minimum:** **-Name of the person evaluated** **-Evaluation date and time** **-Media and components used including manufacturer, expiration date, and lot number** **-Starting temperature for each interval of incubation** **-Dates of incubation** **-Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing)** **-Results of the evaluation and any corrective actions** **-Name of the observer and personnel reading and documenting the results**

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	N/A	There were no failures observed.
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	N/A	There were no failures observed.

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#3	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	N/A	There were no failures.
#4	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	There were no failures.
#5	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	There were no failures.
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions	Hand Hygiene and Garbing Competency Evaluation (Section 2.2)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. **2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.** **3. Select the appropriate response for each item reviewed.** **-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.** **-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.** **-Select "Missing" if the document is not present in the file.** **-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.** **4. Use the notes column to document any pertinent information.**	**USP requirements:** **1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands.** **2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row.** **3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth.** **4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days.** **5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands.** **6. Documentation includes, at minimum:** **-Name of the person evaluated** **-Evaluation date and time** **-Media and components used including manufacturer, expiration date, and lot number** **-Starting temperature for each interval of incubation** **-Dates of incubation** **-Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT)** **-Results of the evaluation and any corrective actions** **-Name of the observer and personnel reading and documenting the results**

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	N/A	There were no failures.
#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Yes	Yes	Yes	Yes	

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#2	Pharmacist	Supervising/Direct Oversight	Category 2 only	Missing	Missing	Missing	Missing	The files required for this training were locked in the PIC's desk and were not available for review.
#3	Pharmacist	Supervising/Direct Oversight	Category 2 only	Missing	Missing	Missing	Missing	The files required for this training were locked in the PIC's desk and were not available for review.
#4	Pharmacy Technician	Compounder	Category 2 only	Missing	Missing	Missing	Missing	The files required for this training were locked in the PIC's desk and were not available for review.
#5	Pharmacy Technician	Compounder	Category 2 only	Missing	Missing	Missing	Missing	The files required for this training were locked in the PIC's desk and were not available for review.
#6								
#7								
#8								
#9								
#10								

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.

- Recommend also pulling supervising personnel file.

- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).

Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.)

- *Note: long-term employees may not have initial training available, if this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.

Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions	Demonstrating Knowledge and Competency of Core Skills (Section 2.1)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1. Personnel who perform or oversee compounding *or support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2). 2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas: -Hand hygiene -Garbing -Cleaning and disinfection -Calculations, measuring, and mixing -Aseptic technique -Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components) -Use of equipment -Documentation of the compounding process (eg, master formulation and compounding records) -Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area -Proper use of PECs -Principles of movement of materials and personnel within the compounding area 3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3). 4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3). 5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Supervising/Direct Oversight	Category 2 only	Missing	Missing	Missing	Missing	The files required for this training were locked in the PIC's desk and were not available for review.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). Use the records tab to document records reviewed.			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	No		2, 2.1, 17 Table 2, Table 3

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Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to the compliance statements.***	N/A	All product is held and not released until testing results are obtained.	18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	N/A		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	N/A		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	N/A		18.1

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Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20

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Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20

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Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1

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Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3
	Quality Assurance and Quality Control			**18**
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18 USP <1163>

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Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	Yes		12.2, 12.3
	CSP Packaging, Shipping and Transport			**19**
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2

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		Observation	Inspector Notes	USP Reference(s)
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	Yes		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	N/A		12.3
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	Yes		12.3 Table 13 USP <85>

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		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	Yes		12.3 USP <85>

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		Observation	Inspector Notes	USP Reference(s)
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."*** ***Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	N/A		12.2 USP <71>, <1223>

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		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	N/A	Only single dose CSPs are compounded.	12.2, 14.2.3 USP <71>

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		Observation	Inspector Notes	USP Reference(s)
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	N/A		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	N/A		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			**12**
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	N/A		14.5 USP <51>

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		Observation	Inspector Notes	USP Reference(s)
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	N/A		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	N/A		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	N/A		14.5

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		Observation	Inspector Notes	USP Reference(s)
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>

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		Observation	Inspector Notes	USP Reference(s)
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>

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		Observation	Inspector Notes	USP Reference(s)
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14

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		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3

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		Observation	Inspector Notes	USP Reference(s)
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, Table 13
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 13
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
	Establishing BUDs			14
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A	There is no SCA.	14.3, Table 12

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	N/A	There are no multi-dose products compounded.	13
71.12	Labeling includes the route of administration, as applicable.	Yes		13
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>

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		Observation	Inspector Notes	USP Reference(s)
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include...Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	N/A	There are no immediate use CSPs.	11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes	The BUD is part of the template design.	11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			11
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to the compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	N/A	All CSPs are patient specific.	11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	N/A		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	N/A		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	N/A		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	N/A		10.1 USP <1228.4>

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		Observation	Inspector Notes	USP Reference(s)
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20

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		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4

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		Observation	Inspector Notes	USP Reference(s)
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	Yes		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	Yes		10.3, 20

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		Observation	Inspector Notes	USP Reference(s)
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A	Steam sterilization is used only for equipment.	10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	Yes		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	Yes		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	N/A	Steam sterilization is used only for equipment.	10.3 USP <1229.5> USP <1229.9>

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		Observation	Inspector Notes	USP Reference(s)
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes	Steam sterilization is used only for equipment.	10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A	Steam sterilization is used only for equipment.	10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	Yes		10.3

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		Observation	Inspector Notes	USP Reference(s)
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	Yes		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2

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		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."	Yes		10.2

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		Observation	Inspector Notes	USP Reference(s)
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.2 USP <1229.4>

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7
	Sterilization and Depyrogenation			**10**
63.0	Does the pharmacy compound preparations with any nonsterile starting components? ***If the pharmacy does not compound preparations with any nonsterile starting components, inspector should answer question as N/A.***	Yes		10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Chartwell Pennsylvania, LP dba Chartwell Pennsylvania

e-Profile ID: 802348

Inspection Date: 05/20/2024 - 05/21/2024

		Observation	Inspector Notes	USP Reference(s)
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 01865	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: AH8572984 ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Hartley Medical Center Pharmacy, LLC

Physical Address: 113 W. Victoria St

City: Long Beach State: CA Zip: 90805

Mailing Address (if different from physical address): _____

City: 4 Creek Parkway State: PA Zip: 19061

Telephone: Boothwyn Toll Free # (NAC 639.708, NRS 639.23286): 800-223-4376

Fax: 800-355-1029 Contact Email: pharmacyregulatory@pentechealth.com

Website: www.hartleymedical.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): William Stuart

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 09062

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: William Stuart	NV Pharmacist Registration #: 09062
Name: Vy Ninh	NV Pharmacist Registration #:
Name: Mirian Paik	NV Pharmacist Registration #:
Name: Amy Trinh	NV Pharmacist Registration #:
Name: Helen Truong	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Pentech Holdings, Inc

Corporation/Organization Name: Hartley Medical Center Pharmacy, LLC

Mailing Address: 4 Creek Parkway

City: Boothwyn State: PA Zip: 19061

Telephone: 800-223-4376 Email: pharmacyregulatory@pentechealth.com

Contact Person Name: Sara Sergei

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Hartley Medical Center Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Matthew Deans

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

09/30/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Deans

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

09/30/2025
Date

Board Use Only	Date Received: 10/1/25	Amount: $500 ck 031963

HARTLEY MEDICAL CENTER PHARMACY, INC.
DISCIPLINARY DISCLOSURES

The below describes the disciplinary history for Hartley Medical Center Pharmacy, Inc. ("Hartley"):

2010 COLORADO NONCOMPLIANCE

In a Final Order entered May 17, 2010, the Colorado Board of Pharmacy disciplined Hartley for noncompliance with the Board's prescription drug monitoring program rules. For the periods of October 16, 2009, through October 25, 2009 and March 16, 2010, through, March 25, 2010, Hartley did not submit a zero report indicating no dispensing of prescriptions for the respective periods. A fine of $5,500 was paid to the State of Colorado and no further action was taken. (Colorado Board of Pharmacy - Case No. 2010-003639; License #: OSP 5641)

2010 CALIFORNIA CITATION

In a Citation issued October 4, 2010, the California State Board of Pharmacy cited Hartley for using an expired ingredient to compound a medication. Under California law, this citation is not considered a disciplinary action for reporting purposes. (California Board of Pharmacy – Citation No. CI 2009 41822; License #: PHY 20643)

The below action was a reciprocal action taken by a state regulator as a result of Hartley's alleged failure to report the 2010 California Citation matter described above:

- *Colorado Board of Pharmacy – DORA Case No. 2016-296 (Final Order Entered June 30, 2016; License # OSP 5641)* – Hartley paid a fine of $2,300 to settle allegations by the Colorado Board of Pharmacy that Hartley failed to timely report the 2010 California Citation.

The below actions were reciprocal actions taken by state regulators as a result of Hartley's alleged failure to report the 2010 Colorado Noncompliance and the 2010 California Citation matters described above:

- *Hawaii – Regulated Industries Complaints Office Case No. PHA 2015-34-L (Settlement Agreement approved January 21, 2016; License #: PMP 607)* - Hartley paid a fine of $1,500 to settle allegations by the Hawaii Regulated Industries Complaints Office that Hartley failed to timely report the 2010 Colorado Noncompliance and 2010 California Citation.
- *Michigan Board of Pharmacy – Case No. 53-16-140779 (Consent Order Dated December 7, 2016; License #: 53-01-009562)* – The Michigan Board of Pharmacy found Hartley in violation of state law which provides for reciprocal disciplinary action based on the 2010 Colorado Noncompliance and 2010 California Citation. As part of a consent order, Hartley paid a fine of $500.00.

2015 FDA FORM 483 LETTER

In 2015, FDA inspected Hartley and found it in violation of certain provisions of Section 503A and issued a Form 483 Letter – Notice of Inspectional Deficiencies to Hartley – which noted inspectional deficiencies based on Hartley's clinical compounding processes.

2016 FDA WARNING LETTER

After a voluntary recall due to Hartley's observation that certain drugs were compounded using a laminar flow hood that was malfunctioning, the FDA issued Hartley a Warning Letter on April 21, 2016. Among the allegations in the Warning Letter were several quality control issues associated with Hartley's compounding processes and an allegation Hartley was dispensing prescription drugs without receiving individually-identified prescriptions. On September 26, 2017, the FDA issued a Close Out letter to Hartley, noting that Hartley had adequately addressed the concerns in the Warning Letter. (FDA WL #29-16).

The below action followed the FDA Warning Letter:

- *Alabama Board of Pharmacy - Case No. 16-L-0121 (Agreement Entered August 31, 2017; License # 113250)* – Hartley reached a settlement agreement with the Alabama Board of Pharmacy ("Board") to resolve disciplinary action related to the allegations contained in the FDA Warning Letter. As part of the agreement, Hartley's Alabama license was placed on probation and Hartley agreed to not renew following expiration of the license.

  The below actions were reciprocal actions taken by state regulators as a result of Hartley's alleged failure to report the Alabama matter described above:

  - *Colorado Board of Pharmacy - Case No. 2017-1186 (Letter of Admonition Dated March 16, 2018; License #OSP 5641)* – Hartley reached a settlement agreement with the Colorado Board of Pharmacy ("Board") to resolve allegations that Harley failed to timely notify the Board of the disciplinary action taken by the Alabama Board of Pharmacy. As part of the agreement, Hartley received a letter of admonition from the Board.
  - *Texas Board of Pharmacy - Case No. L-17-027 (Agreed Order Entered August 7, 2018; License #: 26729)* – Hartley and the Texas Board of Pharmacy negotiated an Agreed Board Order to resolve disciplinary action initiated in response to the action taken by the Alabama Board of Pharmacy. As part of the order, Hartley paid a $5,000 fine and Hartley's license was publicly reprimanded.

Hartley Medical Center Pharmacy, Incorporated - Close Out Letter 9/26/17



FDA U.S. FOOD & DRUG ADMINISTRATION

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road
Los Angeles, California 92612
Telephone: (949) 608-2900
Fax: (949) 608-4415

VIA UNITED PARCEL SERVICE

September 26, 2017

William Stuart, Owner/President
Hartley Medical Center Pharmacy, Inc.
113 W. Victoria Street
Long Beach, CA 90805-2162

Dear Mr. Stuart:

The U.S. Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our warning letter [WL #29-16] dated April 21, 2016. Based on our evaluation, it appears that you have adequately addressed the violations contained in this warning letter.

You are expected to take all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,
/S/

Acting for CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax: (949)608-4417	3/20/2017-3/24/2017
	FEI NUMBER 3011630209

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
William A. Stuart, RPh , President	
FIRM NAME Hartley Medical Center Pharmacy, Incorporated	STREET ADDRESS 113 W Victoria St
CITY, STATE, ZIP CODE, COUNTRY Long Beach, CA 90805-2162	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

Observation 1) Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically,

The repeater pump used to dispense drug stocks into smaller unit vials is wheeled from the ISO-7 Ante room to the ISO-6 IV Clean Room when needed and wheeled back to the Ante room when not needed.

Observation 2) The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

I observed that gaps in the emergency exit double doors from the ISO-6 IV room are sealed with tape, but there were some areas where the tape had been worn or was not fully maintaining the seal, thus possibly compromising the integrity of the ISO-6 room.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Roger F Zabinski, Investigator	DATE ISSUED 3/24/2017

X Roger F Zabinski
Roger F Zabinski
Investigator
Signed by: Roger F. Zabinski

hartleymedical

113 W. Victoria St.
Long Beach, CA, 90805-2162
562-595-7548

VIA EMAIL AND FEDEX

Friday, March 31, 2017
Mr. Steven Porter
Director
Los Angeles District
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

RE: Hartley Medical Center Pharmacy Inc. Response to FDA Form 483 Issued March 24, 2017

Dear Mr. Porter,

On behalf of Hartley Medical Center Pharmacy Inc., I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's website. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of U.S.C. § 1905, 21 U.S.C. § 331 (0), and 5 U.S.C. § 552 (b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: Hartley Medical Center Pharmacy Inc. letter dated 03/31/2017 excluding attachments/tables, which responds to FDA's Form 483 dated 03/24/2017.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Hartley Medical Center Pharmacy Inc. and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,

William A. Stuart, RPh
President
Hartley Medical Center Pharmacy, Inc.
113 West Victoria St
Long Beach, CA 90805
Telephone: (562) 595-7548
Facsimile: (562) 595-9855

hartleymedical

113 W. Victoria St.
Long Beach, CA, 90805-2162
562-595-7548

VIA EMAIL AND FEDEX

Friday, March 31, 2017
Mr. Steven Porter
Director
Los Angeles District
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

RE: Hartley Medical Center Pharmacy Inc. Response to FDA Form 483 Issued March 24, 2017

Dear Mr. Porter,

This letter is in response to the FDA Observation Form FDA-483 issued on March 24, 2017 regarding the inspection of our facility located at 113 W. Victoria St., Long Beach, CA 90805. The inspection was conducted between March 20, 2017 through March 24, 2017. After this inspection, a FDA Form 483 was issued which includes two (2) Observations.

The following are the responses to the FDA's Observations. We respectfully request that this response, excluding any attachments, be posted on the FDA's website as well as every time a copy of Hartley Medical Center Pharmacy's FDA Form 483 is provided to an entity outside of the FDA. This response is to entail all of Hartley Medical Center Pharmacy's responses and remediation to all the Observations made on the FDA Form 483 issued March 24, 2017.

We look forward to working together with the FDA to supply patients with highest quality products as we continue to accommodate patient needs. Hartley Medical Center Pharmacy has always demonstrated a high standard of quality in patient care and we welcome this opportunity to take our facility to the next level of excellence. If there are any questions or concerns in regards to our response, please contact as soon as possible.

Sincerely,

William A. Stuart, RPh
President
Hartley Medical Center Pharmacy, Inc.
113 West Victoria St
Long Beach, CA 90805
Telephone: (562) 595-7548
Facsimile: (562) 595-9855

Phillip Ing
Quality Assurance Specialist
Hartley Medical Center Pharmacy, Inc.
113 West Victoria St
Long Beach, CA 90805
Telephone: (562) 595-7548
Facsimile: (562) 595-9855

Detailed Response to the Form 483 Letter Dated March 24, 2017

NOTE: FDA Form 483 text is represented in ***Bold, Italic*** text.

OBSERVATION 1

Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically,

The repeater pump used to dispense drug stocks into smaller unit vials is wheeled from the ISO-7 Ante room to the ISO-6 IV Clean Room when needed and wheeled back to the Ante room when not needed.

Response 1:
Hartley Medical Center Pharmacy Inc. agrees with the FDA's observation. The repeater pump is affixed to a stand with wheels that is occasionally moved from the ISO-6 and ISO-7 cleanroom areas. The repeater pump and stand will strictly stay in the ISO-6 buffer room and will not be removed unless repairs are needed or its use is discontinued. If the repeater pump is removed from the ISO-6 area, it will be cleaned appropriately with sterile 70% isopropyl alcohol upon its return. Regardless, the repeater pump and stand will be cleaned on a weekly basis and before each use. These changes will be reflected in an updated SOP #1.05 (Attachment 1) as well as the cleaning log (Attachment 3). Staff have been trained and notified on the revision of SOP #1.05. (Attachment 2).

OBSERVATION 2

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

I observed that gaps in the emergency exit double doors from the ISO-6 IV room are sealed with tape, but there were some areas where the tape had been worn or was not fully maintaining the seal, thus possibly compromising the integrity of the ISO-6 room.

Response 2:
Hartley Medical Center Pharmacy Inc. agrees with the FDA's observation. The tape that is mentioned in Observation 2 is located on the exterior of the cleanroom, which is not an ISO-classified area. The tape is used to prevent any particles, vermin, and / or debris from entering the ISO-6 area. The tape will be changed on a routine basis from now on. The frequency of this will be monthly unless a significant amount of wear and tear is visibly seen on the tape. This policy will be reflected in an updated SOP #1.00 (Attachment 3). Staff have been trained and notified on the revision of SOP #1.00. (Attachment 2).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	06/29/2015 - 07/08/2015* FEI NUMBER 3011630209

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William A. Stuart, RPh, President

FIRM NAME	STREET ADDRESS
Hartley Medical Center Pharmacy, Incorporated	113 W Victoria St
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Long Beach, CA 90805-2162	Producer of sterile drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

a. No goggles are worn during the preparation of sterile drug products which allows exposed skin around the neck and eyes.
b. Non-sterile gowning materials (scrub pants, scrub jacket, bouffant, and face mask) are worn in the aseptic area during preparation of sterile products.
c. The firm allows the clean room pants and jackets to be re-used throughout the day.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, personnel monitoring and surface sampling in the LAF hoods is not performed each day that final drug products are prepared.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

a. No sporicidal agent is used in the cleanroom.
b. [redacted] (b) (4) Germicidal Solution used to clean the aseptic area are not rendered sterile prior to use.
c. The firm uses non sterile (b) (4) to clean the surfaces of the LAF hoods where drug products are prepared.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Caryn M. Mcnab, Investigator Caryn M. McNab Jennifer M. Gogley, Microbiologist Jennifer M. Gogley Drew M. Love, Consumer Safety Officer	07/08/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	06/29/2015 - 07/08/2015* FEI NUMBER 3011630209

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William A. Stuart, RPh, President

FIRM NAME	STREET ADDRESS
Hartley Medical Center Pharmacy, Incorporated	113 W Victoria St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Long Beach, CA 90805-2162	Producer of sterile drugs

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, the firm's media fills do not simulate the batch process in which up to (b) (4) The current media fills only simulate the preparation of a patient specific drug product in which (b) (4)

OBSERVATION 5

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

A. There is no endotoxin testing of the final drug product in the pre-filled syringe or of the (b) (4) at the time of dispensing to assure that the endotoxin level of the drug product delivered to the patient remains within the established specification (b) (4). Drug (b) (4) such as preservative free Fentanyl Citrate, Clonidine, and Baclofen for intrathecal use are (b) (4) (b) (4) (b) (4) are tested for (b) (4) at the time of (b) (4); however the firm (b) (4).

B. Suitability testing for the sterility test method, necessary to demonstrate that the product does not interfere with the test, has not been performed by the contract testing laboratory which conducts the release test. For example:
   i. Clonidine HCL 2mg/ml lot number CL7106AB was prepared on 5/11/15. Sterility testing was performed by a contract lab however no suitability testing per USP <71> has been performed for this formulation.
   ii. Fentanyl Citrate 25mg/ml lot number FE8154 was prepared on 5/22/15. Sterility testing was performed by a contract lab however no suitability testing per USP <71> has been performed for this formulation.
   iii. Morphine Sulfate 50mg/ml lot number MS2226 was prepared on 6/2/15. Sterility testing was performed by a contract lab however no suitability testing per USP <71> has been performed for this formulation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Caryn M. Mcnab, Investigator Caryn M. McNab Jennifer M. Gogley, Microbiologist Jennifer M Gogley Drew M. Love, Consumer Safety Officer	07/08/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	06/29/2015 - 07/08/2015* FEI NUMBER 3011630209

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William A. Stuart, RPh, President

FIRM NAME	STREET ADDRESS
Hartley Medical Center Pharmacy, Incorporated	113 W Victoria St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Long Beach, CA 90805-2162	Producer of sterile drugs

OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug product containers, closures, and in-process materials conform to appropriate standards of identity, strength, quality and purity.

Specifically, the firm has not performed suitability testing for the sterility test methods used during in-process testing of drug (b) (4) that are intended to demonstrate the solutions remain sterile at (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) . In addition, the sterility test conducted at the (b) (4) (b) (4) does not include fluid thioglycollate media, instead only (b) (4) is used.

*** DATES OF INSPECTION:**
06/29/2015(Mon), 06/30/2015(Tue), 07/01/2015(Wed), 07/08/2015(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Caryn M. Mcnab, Investigator Caryn M. McNab
Jennifer M. Gogley, Microbiologist Jennifer M Gogley
Drew M. Love, Consumer Safety Officer

DATE ISSUED: 07/08/2015

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2009 41822	HARTLEY MED CTR PHCY INC, PHY 20643

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4169 subd. (a)(4)	Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after or beyond use date on the label	$500.00
CCR, Title 16, § 1716.2 subd. (a)(3)	Record requirements - Compounding for future use - The expiration date of the finished product	$500.00

CONDUCT:

Using Expired Ingredients to Compounded Medication Prohibited. Business and Professions Code section 4169, subsection (a) part 4, Prohibited Acts-Selling Expired Medication, prohibits a pharmacy from purchase, trade, sell, or transfer of a dangerous drug after the beyond use date on label. Hartley Med Ctr Phcy (PHY 20643) failed to comply. Specifically on 10-1-09, Hartley Med Ctr Phcy (PHY 20643) located at 113 W. Victoria Street in Long Beach, 90805 compounded BLT (Benzocaine, Lidocaine, Tetracaine) cream (Lot# BLT-009) using an expired ingredient:

Polysorbate 80	expires 8/09

This is a violation of pharmacy law.

Labeled Expiration Date Exceeds Ingredient Expiration Date. California Code of Regulations section 1716.2 subsections (a) part 3, Record Requirements for Compounding-Expiration Date requires the compounding pharmacy to maintain a record of the expiration date of the finished product. The expiration date can not exceed 180 days or the shortest expiration date of any ingredient use to compound the finished product. Hartley Med Ctr Phcy (PHY 20643) failed to comply. Specifically, on or about 7-31-09, Hartley Med Ctr Phcy (PHY 20643) located at 113 W. Victoria Street in Long Beach, 90805 compounded BLT (Benzocaine, Lidocaine, Tetracaine) cream (Lot# BLT-008) using 3 short dated ingredients that expired before the product's labeled expiration date of 1-31-10.

DMSO	expires 11/09
Polysorbate 80	expires 8/09
Lavender Oil	expires 8/09

This is a violation of pharmacy law.

CITATION ISSUED ON: October 04, 2010 TOTAL AMOUNT OF FINE(S): $1,000.00

PAYMENT OF FINE(S) DUE BY: November 03, 2010

California State Board of Pharmacy
1625 N. Market Blvd., Ste. N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8617
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

CERTIFICATION OF DOCUMENTS

I, Virginia Herold, hereby certify under penalty of perjury that the following attached documents are true and correct copies of the original documents and/or copies on file in the office of the California State Board of Pharmacy located at 1625 North Market Blvd, Suite N219, Sacramento, CA 95834:

1. Copy of Citation and Fine Order, CI 2009 41822, issued to Hartley Med Ctr Phcy Inc., PHY 20643 on October 4, 2010.

Witness My Hand and Seal of the
California State Board of Pharmacy
This 24th day of May 2016

Virginia Herold

VIRGINIA HEROLD
Executive Officer
California State Board of Pharmacy

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
HARTLEY MEDICAL CENTER PHARMACY, INC.	)	BOARD OF PHARMACY
	)	
	)	
Non-Resident Pharmacy Permit Number 113250	)	Case Number 16-L-0121

FINAL ORDER

On December 13, 2016 this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board"), on a Complaint against Hartley Medical Center Pharmacy, Inc. (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Findings of Fact

1. The Respondent is a non-resident pharmacy which was issued permit number 113250. (Board's Exhibit Two)

2. The Respondent was notified of the charges on October 24, 2016; the Respondent was represented at the administrative hearing by counsel, Ms. Rhonda H. Lacey, Esq. The Respondent's president and chief executive officer, Mr. William Stuart also attended the administrative hearing. . (Board's Exhibits One and Two)

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. From June 29, 2015 through July 8, 2015 the Food and Drug Administration (FDA)) inspected the Respondent's facilities; the FDA subsequently issued a FDA Form 483 listing six observations showing deficiencies in the Respondent's processing and handling of sterile compounded products. (Board's Exhibit Three).

5. On April 21, 2016 the Food and Drug Administration of the Public Health Service (FDA) issued to the Respondent a Warning letter based on the June 29, 2015 through July 8, 2015 inspection. (Board's Exhibit One "A")

6. The April 21, Warning letter, among other things, stated the following:

(a) valid prescriptions for individually-identified patients for a portion of the drug products you were producing were not received.

(b) serious deficiencies in your practices for producing sterile drug products, which put patients at risk were observed, including the Respondent produced sterile from non-sterile components and then stored them in containers, which were subsequently punctured multiple times throughout the assigned expiry period, puncturing a container compromises the integrity of the container closure system, and each puncture increases the chances of contamination.

(c) the Respondent's production process observed at its facility, including the storage conditions, represents a potential lack of control for bioburden and further sterilization performed by the Respondent would not remove bacterial endotoxin of particular concern as some of the drug products the Respondent produced from solutions were intended for intrathecal administration and the Respondent do not test each of its finished drug products to ensure that the amount of endotoxin is within an acceptable limit.

(d) The Respondent did not use a sporicidal agent or sterile wipes, and used non-sterile sanitizers as part of its disinfection program for the aseptic processing areas posing a significant contamination risk.

(Board's Exhibit One "A")

7. On November 17, 2016 the FDA issued a recall alert for the recalling of several lots of Respondent's product Prolotherapy with Phenol based on non-sterility concerns for the products. (Board's Exhibit Four)

8. In addition to the Prolotherapy with Phenol recall, the Respondent recalled multiple other products including hydromorphone, hydromorphone with bupivacaine, sufentanil with clonidine, fentanyl with baclofen and bupivacaine and clonidine, hydromorphone with fentanyl, among others. (Board's Exhibit Five)

9. The Respondent was inspected On November 16-17, 2016 by the National Association of Boards of Pharmacy for sterile compounding where the Respondent was found deficient in its use of beyond use dates and non-compliant with standards related to stock solutions, cleaning of sterile preparation hoods, high risk compounding tests and testing of performance of sterile preparation hoods. (Board's Exhibit Six)

10. From its website, the Respondent's New Customer Agreement shows that it sells to entities other than on patient specific requests. (Board's Exhibit Seven)

11. The Respondent's testing of sterile products is inadequate including testing of and use of multiple dose products. (Board's Exhibits One "A, Six, Eight, Nine, Eleven, Twelve, Thirteen and Fifteen)

12. Training of personnel and/or document of such training for sterile compounding by the Respondent is inadequate. (Board's Exhibits One "A", Three, Ten and Seventeen)

13. The Respondent's use of beyond use dating for sterile products does not meet appropriate and accepted standards. (Board's Exhibits Six, Fourteen and Sixteen)

14. The cleaning of the Respondent's aseptic preparation areas and equipment fails to meet appropriate and accepted standards. (Board's Exhibits Three, Six, Seventeen and Eighteen)

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction in this cause pursuant to Code of Alabama (1975), § 34-23-34, § 34-23-92 (12), § 20-2-213 (e) and § 41-22-12.

2. The Respondent was properly notified of the charges.

3. The Respondent made no objection to the timeliness of the Notice of Hearing.

4. The Respondent made no objection to the specificity of the Statement of Charges

5. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 34-23-33 (2) in that it violated 503A, 505 (a), 502 (f) (1), 301 (a), (d) and/or (k) of the FDCA as more fully set out in a Warning Letter from the FDA dated April 21, 2016.

The Board finds that each violation of any provision of the FDCA is a separate and distinct violation of Code of Alabama (1975), § 34-23-33 (2).

6. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § § 34-23-33 (13) in that it violated Board Rule 680-X-2.22 (2) (d) based upon any or all of the violations of the preceding paragraph of this Final Order.

7. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 34-23-33 (2) in that it violated 501(a) (2) (A) and/or 301 (a) and/or (k) of the FDCA relating to sterility and ensuring aseptic technique, practices and/or conditions in connection with sterile compounding operations.

The Board finds that each violation of any provision of the FOCA is a separate and distinct violation of Code of Alabama (1975), § 34-23-33 (2).

8. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 34-23-33 (13) in that it violated Board Rule 680-X-2.22 (2) (a) based upon any or all of the violations of paragraph seven above of this Final Order.

9. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 34-23-33 (13) in that it violated Board Rule 680-X-2.22 (2) (b) based upon any or all of the violations of paragraph seven above of this Final Order.

10. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 34-23-33 (13) in that it violated Board Rule 680-X-2.22 (2) (d) based upon any or all of the violations of paragraph seven above of this Final Order.

11. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 34-23-33 (13) in that it violated Board Rule 680-X-2.22 (2) (f) based upon any or all of the violations of paragraph seven above of this Final Order.

12. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 34-23-33 (6) based upon any or all of the violations of the preceding paragraphs of this Final Order.

13. The Respondent's non-resident pharmacy permit is due to be REVOKED in that it is guilty of violating Code of Alabama (1975), § 20-2-54 (a) (4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of the violations contained in the preceding paragraphs of this Final Order.

ORDER

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby

ORDERED as follows:

1. The Respondent's non-resident pharmacy permit is hereby REVOKED.

DONE and ORDERED, this 22nd day of December 2016.

Timothy A. Martin, Pharm. D., President
Alabama State Board of Pharmacy

Copies to:
Ms. Rhonda Lacey, Esq.
Ms. Mitzi Ellenburg, Director of Operations
Ms. Patty Wright, Case Coordinator
Mr. James S. Ward, Esq.
Mr. Vance L. Alexander, Esq.

AGREEMENT

This Agreement is entered into this 31st day of August, 2017, by and between the Alabama State Board of Pharmacy (Board) and Hartley Medical Center Pharmacy, Inc. (Hartley).

WHEREAS, the Board entered a Final Order (Order) in Case No. 16-L-0121 on December 22, 2016 revoking the Non-Resident Pharmacy Permit number 113250 issued to Hartley.

WHEREAS, Hartley has filed a Petition for Judicial Review in the Montgomery County Circuit Court in a case styled Hartley Medical Center Pharmacy, Inc. v. Alabama State Board of Pharmacy, Case No. CV-2017-900284 (the Appeal).

WHEREAS, the parties are mutually desirous of resolving the issues asserted in the Appeal and to settle their differences without the need for protracted litigation through the terms set out below.

BY THE EXECUTION OF THIS AGREEMENT IT IS THEREFORE UNDERSTOOD AND AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. The Board agrees to Amend its Order to reflect the sanction as suspension of Hartley's Non-Resident Pharmacy Permit number 113250 with immediate reversion to probation and report the same to the National Practitioner Data Bank (NPDB). In all other respects, the Order remains unchanged.

2. Hartley's Non-Resident Pharmacy Permit number 113250 has expired, and Hartley voluntarily agrees to never renew or seek reinstatement of its permit or to own in whole or in part any pharmacy which requires a permit to do business in the State of Alabama. The Board 's website will reflect that Hartley's permit is "inactive."

3. Hartley agrees to dismiss the Appeal with prejudice.

Buddy Bunch, R.Ph., President
Alabama State Board of Pharmacy

William Stuart, Owner
Hartley Medical Center Pharmacy, Inc.

1"A" - FDA Warning Letter
2 - Scheduling order delivery certification
3 - 483
4 - Prolotherapy Recall
5 -LAFW Recall
6 - VPP Inspection
7 - New Customer Agreement
8 - PF Vial
9 - Single vs Multi-dose vials
10 - Single Use SOP
11 - CDC - single use
12 - Quality Testing SOP
13 - Pyrogen and edotoxin guidance
14 - BUD SOP
15 - UPS section on Sterility testing
16 - VPP Re-classification as high risk
17 - Photos from VPP inspection
18 - Cleaning SOP

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy

March 16, 2018

Hartley Medical Center Pharmacy
Attn: William Stuart
113 W. Victoria St.
Long Beach, CA 90805-2162
Email: compliance@hartleymedical.com

Re: Case No. 2017-1186
Registration No. OSP 5641

Dear Pharmacy:

On March 17, 2016, the State Board of Pharmacy ("Board") reviewed the above-referenced case.

After careful consideration of the allegations and corresponding evidence before the Board, the Board determined that, on December 22, 2016, the Alabama Board of Pharmacy ("Alabama Board") entered a Final Order initially revoking your registration in the State of Alabama. The Alabama Board's action arose from a warning letter issued on April 21, 2016, by the Food and Drug Administration ("FDA") following a June 29-July 8, 2015, inspection. The Alabama Board's findings supporting its decision included: (a) valid prescriptions for individually-identified patients for some drug products produced were not received; (b) serious deficiencies in the practices for producing sterile drug products were observed; (c) the production process observed, including the storage conditions, represented a potential lack of control for bioburden; and (d) sterile wipes were not used and non-sterile sanitizers were used as part of the disinfection program for the aseptic processing areas.

You did not timely notify the Board of the Alabama Board's actions.

In mitigation, you note that, on January 10, 2017, the FDA sent a letter concluding "it appears" the deficiencies noted in the warning letter had been addressed. On September 13, 2017, the Alabama Board amended its discipline to remove the sanction of revocation and impose a suspension with probation. On September 26, 2017, the FDA sent a close-out letter, after a March 20-24, 2017, inspection, having found that the deficiencies cited in the warning letter had been "adequately addressed".

After thorough review, the Board found probable cause to believe that you violated sections 12-42.5-123(1)(c)(I-II), (g), and (q), C.R.S., and Rule 9.00.10(b), and are therefore subject to discipline pursuant to section 12-42.5-124, C.R.S.. The Board issues this letter of admonition in accordance with section 12-42.5-124(6)(a), C.R.S.

By this letter, the Board takes the formal disciplinary action of admonishing you for the conduct specified above, and warns you that repetition of such practice may lead to imposition of more severe disciplinary action. This letter of admonition shall be made a part of the permanent records of the Board. This letter is an open public record and a reportable action to individuals or entities requesting disciplinary information. The Board strongly encourages you to review and

understand the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Practice Act requirements and obligations for the practice of prescription drug outlets in Colorado.

You are advised that this letter is in lieu of a formal hearing. Pursuant to your agreement with the Board, you have accepted this letter of admonition and agreed to waive the right provided by section 12-42.5-124(6)(b)-(c), C.R.S., to request that the Board initiate formal disciplinary proceedings to adjudicate the propriety of the conduct upon which the letter of admonition is based.

Sincerely,

FOR THE STATE BOARD OF PHARMACY

Wendy Anderson
Program Director

Cc: Richard Murray, Esq.
Counsel of Record for the Pharmacy

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

Management Branch
Office of Enforcement Expedited Settlement

June 6, 2016

Via U.S. Mail and Email (wstuart@hartleymedical.com)
Hartley Med. Ctr. Pharmacy Inc.
Attn: William A. Stuart, Pharmacist Manager
113 West Victoria Street
Long Beach, CA 90805-2162

Re: Colorado Board of Pharmacy; Case No. 2016-296

Dear Mr. Stuart:

The Colorado State Board of Pharmacy reviewed the available material concerning the complaint filed against the above-mentioned pharmacy. Upon thorough review and discussion, the Board found reasonable cause that the pharmacy violated Sections 12-42.5-123(1)(c), (g) and (q), C.R.S. and Board Rules 9.00.10(b), 21.00.10(b) and 21.10.60(a). In order to promptly resolve the complaint, the Board has referred this disciplinary action to the Expedited Settlement Process ("ESP") along with settlement terms.

The Board would prefer to settle this disciplinary complaint rather than initiating formal legal proceedings. In lieu of a hearing, the Board is willing to resolve this case by means of a stipulated agreement pursuant to the following terms:

- Stipulation with a fine in the amount of $2,000 plus the statutorily mandated surcharge of 15%, for a total fine amount of $2,300.

The above settlement terms and consequences are more fully explained in the enclosed Stipulation and Final Agency Order (Order). By signing the Order, you agree to the Board's settlement terms and avoid formal disciplinary proceedings.

If you wish to accept the terms of this Order, please do the following:

- READ the entire Stipulation and Final Agency Order;
- SIGN the enclosed Stipulation and Final Agency Order;
- RETURN the signed Stipulation and Final Agency Order by June 20, 2016, to:

This correspondence has been sent to the Respondent and Attorney of Record. If you are represented by counsel, you may want to contact them to discuss this matter. This correspondence is not intended to interfere with any attorney client relationship.

Lauri Rose
Office of Expedited Settlement
1560 Broadway, Suite 880
Denver, CO 80202
Fax: (303) 869-0230
Email: lauri.rose@state.co.us

In reviewing the Order, please be aware that the burden of proof in a disciplinary proceeding is not "beyond a reasonable doubt." Rather, disciplinary proceedings are similar to civil trials where the burden is "by a preponderance of the evidence." This means that the Board must only present sufficient evidence to prove that "more likely than not" the pharmacy violated the practice act.

Please be advised that during this process, you have the right to either represent yourself or to be represented by legal counsel of your choice at your own expense. Also, be aware that the representations in the attached Stipulation do not limit the Board's case if this case should be filed for formal disciplinary proceedings. The Colorado Attorney General may add additional violations that he or she deems appropriate.

Finally, this letter and the Expedited Settlement Process fall under the protection of CRE 408 which excludes evidence of compromise and offers of compromise to prove liability.

Please do not hesitate to contact me at (303) 894-7723 or by email if you have any questions or concerns about this matter.

Sincerely,

Lauri Rose

Lauri Rose
Office of Expedited Settlement
lauri.rose@state.co.us

Enclosure

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2016-296

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION IN THE STATE OF COLORADO OF HARTLEY MED. CTR. PHARMACY INC., REGISTRATION NO. OSP 5641,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Hartley Med. Ctr. Pharmacy Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Number 2016-296, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to provisions of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2016).

2. Respondent Pharmacy was originally registered in the State of Colorado on or about July 31, 2006, being issued registration number OSP 5641, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Pharmacy's address of record with the Board and current location is 113 West Victoria Street, Long Beach, California 90805-2162.

4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.

5. Respondent Pharmacy, a resident pharmacy in California, has been registered with the Board as a non-resident pharmacy since July 31, 2006.

6. On or about October 1, 2009, Respondent Pharmacy compounded a preparation of Benzocaine, Lidocaine, and Tetracaine ("BLT") cream using an expired ingredient, polysorbate 80, which had expired in August 2009.

7. Also on October 1, 2009, Respondent Pharmacy compounded BLT cream using two (2) short-dated/expired ingredients, namely DMSO, which was to expire in November 2009, and polysorbate 80, which had expired in August 2009.

8. On July 31, 2009, Respondent Pharmacy compounded BLT cream using three (3) short-dated ingredients, DMSO, polysorbate 80 and lavender oil, which were to expire in November 2009, August 2009, and August 2009, respectively.

9. On or about October 4, 2010, the California Board of Pharmacy disciplined Respondent Pharmacy for the conduct described above.

10. Respondent Pharmacy failed to report to the Board the discipline it received from the California Board of Pharmacy on October 4, 2010.

11. Respondent Pharmacy's conduct in California as described above would subject Respondent Pharmacy to disciplinary action in Colorado.

12. Respondent Pharmacy admits that its conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Rules and provides grounds for disciplinary action against Respondent Pharmacy's Colorado registration as a prescription drug outlet:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this Article, including commission of an act declared unlawful in section 12-42.5-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs;

(g) Has had his or her license to practice pharmacy in another state revoked or suspended, or is otherwise disciplined or has committed acts in any other state that would subject him or her to disciplinary action in this state;

(q) Has failed to notify the board of any discipline against his or her license in another state within thirty days after the discipline.

12-42.5-124. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that the

applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

Pharmacy Board Rules and Regulations

9.00.10 Reporting

b. All licensees or registrants shall notify the Board in writing within 30 days of any disciplinary action against them in another state. Such notification shall include the following:

1. The state;
2. The jurisdiction;
3. The case name;
4. The case number;
5. A description of the matter and a copy of the indictment or charges;
6. A copy of the discipline; and
7. Proof of completion of any requirements set forth in the order, if applicable.

21.00.10 Limitations and Record-Keeping.

b. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the final compounded product. No expired final compounded product shall be dispensed or distributed.

21.10.60 Components.

a. Compounding personnel shall ascertain that ingredients for compounded products are in compliance with rule 21.00.10(b) and are of the correct identity and appropriate quality using the following information: vendors' labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the Preparation.

13. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

DISPOSITION

14. **Fine with Surcharge.** Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Pharmacy shall pay a fine of Two Thousand Dollars and No Cents ($2,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall

impose an additional surcharge of 15% of this fine. Respondent Pharmacy shall therefore pay a total amount of Two Thousand Three Hundred Dollars and No Cents ($2,300.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board. Respondent Pharmacy shall write its registration number (OSP 5641) and the case number (2016-296) on the check.

15. **Other Requirements.** Through its undersigned Authorized Representative, Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Pharmacy shall:

    a. promptly pay all its own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceuticals and pharmacists in the State of Colorado.

16. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

17. **Completion of Terms.** Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent from the Final Agency Order, and Respondent's registration will be restored to active and unencumbered status.

18. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;

    b. To respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. To appeal this Board order.

Respondent Pharmacy freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

19. **Acknowledgments.** The undersigned Authorized Representative of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

20. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

21. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

22. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative.

23. **Effective Date.** This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Pharmacy at Respondent Pharmacy's address of record with the Board, or (b) service by electronic means on Respondent Pharmacy at Respondent Pharmacy's electronic address of record with the Board. Respondent Pharmacy hereby consents to service by electronic means if Respondent Pharmacy has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Pharmacy

William A Stuart
Authorized Representative / Title

Dated: June 16, 2016

Subscribed and sworn to before me in the County of Los Angeles, State of California, this 16 day of June, 2016, by William A Stuart, in his/her capacity as an authorized agent of Hartley Med. Ctr. Pharmacy Inc.

STACY S. CANCINO
COMM. #2126783
NOTARY PUBLIC - CALIFORNIA
LOS ANGELES COUNTY
My Comm. Expires Oct. 14, 2019

Notary Public

My commission expires: 10/14/2019

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this _____day of _____, 2016.

State Board of Pharmacy

BY: _____
Andrea Faley
Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this _____ day of _____ 2016, addressed as follows:

Hartley Med. Ctr. Pharmacy Inc.
Attn: William A. Stuart, Pharmacist Manager
113 W. Victoria Street
Long Beach, CA 90805-2162
Email: wstuart@hartleymedical.com

_____
Agent of the Board

AGREED BOARD ORDER #L-17-024

RE: IN THE MATTER OF HARTLEY MEDICAL CENTER PHARMACY, INC. (PHARMACY LICENSE #26729)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 26729 issued to Hartley Medical Center Pharmacy, Inc. (Respondent), 113 West Victoria Street, Long Beach, California 90805.

By letter dated March 21, 2017, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.002(a)(3) and (13); and 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015), as alleged in the Count below.

The conduct described in the Final Order of the Alabama State Board of Pharmacy is substantially similar to the conduct described in:

> Section 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015); and
>
> Sections 291.106(15); 291.133(d)(1)(A)(i); 291.133(d)(2); 291.133(d)(6)(F) and (H); 291.133(d)(7)(A)(ii) and (iii); 291.133(d)(12); and 291.133(d)(14)(B)(i) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2016).

COUNT

On or about December 22, 2016, the Alabama State Board of Pharmacy entered a Final Order against the Alabama non-resident pharmacy permit number 113250 held by Hartley Medical Center Pharmacy, Inc. The Order was partly based on Findings of Fact that on November 16 and 17, 2016, an inspection by the National Association of Boards of Pharmacy identified various deficiencies, including noncompliance with stock solution standards, beyond use date standards, cleaning of sterile preparation hoods, high risk compounding tests, and testing of performance of sterile preparation hoods.

An informal conference was held in the Board's office on June 7, 2017, with Marlon Coburn, Compliance Officer; Cheri Huddleston, Legislative Consultant; William A. Stuart, R.Ph., Pharmacist-in-Charge and Corporate President, on behalf of Respondent; and Jay B. Stewart, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: Suzette Tijerina, R.Ph., Board Member; Gay Dodson, R.Ph., Executive

Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin Arnold, General Counsel. Megan Holloway, Staff Attorney, was also in attendance.

Following the informal conference, Respondent submitted information that on September 13, 2017, the Alabama State Board of Pharmacy entered an Amended Final Order against Hartley Medical Center Pharmacy, Inc., which replaced the previously imposed disciplinary action with a probation. Respondent's Alabama Non-Resident Pharmacy Permit, Number 113250, expired on or about December 31, 2016.

By appearing at the informal conference and by signing this Order, William A. Stuart and Respondent's counsel neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent's license is reprimanded.

(2) Respondent shall pay an administrative penalty of five thousand dollars ($5,000) due one hundred twenty (120) days after the entry of this Order.

(3) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(4) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2017), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2018).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 7th day of August · 2018 ·

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

William A. Stuart, R.Ph., Corporate President
On behalf of Hartley Medical Center Pharmacy, Inc.

Jay B. Stewart, Legal Counsel for Hartley Medical Center Pharmacy, Inc.
Hance Scarborough, LLP
400 West 15th Street, Suite 950
Austin, Texas 78701

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

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AGREED BOARD ORDER #L-17-024

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And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 7th day of August · 2018 ·

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

William A. Stuart, R.Ph., Corporate President
On behalf of Hartley Medical Center Pharmacy, Inc.

Jay B. Stewart, Legal Counsel for Hartley Medical Center Pharmacy, Inc.
Hance Scarborough, LLP
400 West 15th Street, Suite 950
Austin, Texas 78701

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

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STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

HARTLEY MEDICAL CENTER PHARMACY
License Number: 53-01-009562

File Number: 53-16-140779
CONSENT ORDER AND STIPULATION

CONSENT ORDER

An Administrative Complaint (Complaint) was executed on June 16, 2016, charging Hartley Medical Center Pharmacy (Respondent Pharmacy) with having violated section 16221(b)(x) of the Public Health Code, MCL 333.1101 et seq.; and

Respondent Pharmacy admits that the facts alleged in the Complaint are true and constitute a violation of the Public Health Code; and

The Disciplinary Subcommittee of the Michigan Board of Pharmacy (Disciplinary Subcommittee) has reviewed the Stipulation and agrees that the public interest is best served by resolution of the outstanding Complaint; therefore,

IT IS FOUND that the facts alleged in the Complaint are true and constitute a violation of section 16221(b)(x) of the Public Health Code, supra.

Accordingly,

IT IS ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Legal Affairs Division, Compliance Section, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-16-140779.**

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 12-7-16

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Pharmacy admits that the facts alleged in the Complaint are true and constitute a violation of section 16221(b)(x) of the Public Health Code, supra.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs (Department) to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Respondent Pharmacy and the Department further agree that this matter is a public record required to be published and made available to the public pursuant to section 11(1)(a) of the Michigan Freedom of Information Act, MCL 15.241(1)(a); and this action will be reported to the National Practitioner Data Bank, and any other entity as required by state or federal law, in accordance with 42 USC 11101-11152.

4. Nichole Cover, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Consent Order.

5. This Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this matter.

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Kim Gaedeke, Director
Bureau of Professional Licensing
Department of Licensing and
Regulatory Affairs

Dated: 11/7/2016

BB

AGREED TO BY:

William A. Stuart
Authorized Representative for
Hartley Medical Center Pharmacy
Respondent Pharmacy

Dated: 11/7/2016

DAVID Y. IGE
GOVERNOR

SHAN S. TSUTSUI
LIEUTENANT GOVERNOR

CATHERINE P. AWAKUNI COLÓN
DIRECTOR

CELIA C. SUZUKI
LICENSING ADMINISTRATOR

STATE OF HAWAII
PROFESSIONAL AND VOCATIONAL LICENSING DIVISION
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
P.O. BOX 3469
HONOLULU, HAWAII 96801
http://cca.hawaii.gov/pvl

January 22, 2016

Hartley Medical Center Pharmacy, Inc.
c/o William A. Stuart, President
113 W. Victoria Street
Long Beach, California 90805

Daria A. Loy-Goto, Staff Attorney
John T. Hassler, Staff Attorney
Regulated Industries Complaints Office
Department of Commerce & Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813

Re: In the Matter of the Miscellaneous Permit of
Hartley Medical Center Pharmacy, Inc.; PHA 2015-34-L

Dear Mr. Stuart, Ms. Loy-Goto and Mr. Hassler:

The Board of Pharmacy, at its meeting on January 21, 2016, approved the above-referenced Settlement Agreement.

Very truly yours,

Lei S. Fukumura

LEI S. FUKUMURA
Special Deputy Attorney General

LSF:jaf

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

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2015 DEC -9 A 9:45
STATE OF HAWAII

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of HARTLEY MEDICAL CENTER PHARMACY, INC., Respondent.	)	PHA 2015-34-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" AND "2"

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent HARTLEY MEDICAL CENTER PHARMACY, INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a miscellaneous permit holder under license number PMP 607. The

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

license was issued on or about July 9, 2009. The license will expire or forfeit on or about December 31, 2015.

2. Respondent's mailing address for purposes of this action is 113 W. Victoria Street, Long Beach, California 90805.

3. RICO received a request for investigation from the Board of Pharmacy after Respondent reported disciplinary action taken by the States of Colorado and California on a November 7, 2011 renewal application submitted to Hawaii.

4. Respondent attached a copy of an October 4, 2010 Citation and Fine issued by the California Board of Pharmacy (Citation No. CI 2009 41822) (hereinafter "the October 4, 2010 California Citation") (Exhibit "1").

5. The October 4, 2010 California Citation was based on allegations Respondent used expired ingredients to compound medication and imposed a $500.00 fine.

6. Respondent also provided a copy of a May 17, 2010 Stipulation and Final Agency Order issued by the Colorado Board of Pharmacy (Case No. 2010-003639) (hereinafter "the Colorado Order") (Exhibit "2").

7. The Colorado Order was based on allegations Respondent failed to comply with drug submission requirements for Colorado's electronic prescription drug monitoring program and imposed a $5,000.00 fine.

8. RICO alleges that disciplinary action was taken against Respondent by the States of Colorado and California and that Respondent failed to timely report the actions.

9. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes

("HRS") § 436B-19(13) (disciplinary action by another state) and § 436B-19(15) (failure to report).

10. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a miscellaneous permit holder by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the October 4, 2010 Citation and Fine issued by the California Board of Pharmacy (Citation No. CI 2009 41822).

6. Respondent represents Exhibit "2" is a true and correct copy of the May 17, 2010 Stipulation and Final Agency Order issued by the Colorado Board of Pharmacy (Case No. 2010-003639).

7. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

8. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

9. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

10. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2015-34-L.

11. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

12. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND FIVE HUNDRED AND NO/100 DOLLARS ($1,500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq.,

235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser

remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

//

//

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: 12, 7, 2015.

HARTLEY MEDICAL CENTER PHARMACY, INC.
Respondent

By: [signature]
Its PRESIDENT

DATED: Honolulu, Hawaii, December 8, 2015.

[signature]
DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF HARTLEY MEDICAL CENTER PHARMACY, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO(S). PHA 2015-34-L; EXHIBITS "1" AND "2"

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF HARTLEY MEDICAL CENTER PHARMACY, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO(S). PHA 2015-34-L; EXHIBITS "1" AND "2"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

Kerri Okamura — 1/21/16

KERRI OKAMURA
Chairperson

DATE

GARRETT A. LAU
Vice Chairperson

Marcella Sn Chock

MARCELLA CHOCK

Mary Jo Keefe

MARY JO KEEFE

Carolyn

CAROLYN S. J. MA

PVL 07/01/15

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles)

On December 7, 2015 before me, Stacy S. Canano
(insert name and title of the officer)

personally appeared William A Stuart,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that he/~~she/they~~ executed the same in his/~~her/their~~ authorized capacity(~~ies~~), and that by his/~~her/their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature _____ (Seal)



DOCUMENT INFORMATION

Document Date 12/7/2015

Number of Pages 17

[X] Placed under Oath [ ] Placed under Affirmation [X] Signed before the Notary

TYPE OF IDENTIFICATION

[ ] Satisfactory Evidence —identification card recorded
[ ] One Credible Witness acknowledging identity of Attorney in Fact
[ ] Two Credible Witnesses acknowledging identity of Attorney in Fact

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2009 41822	HARTLEY MED CTR PHCY INC, PHY 20643

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4169 subd. (a)(4)	Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after or beyond use date on the label	$500.00
CCR, Title 16, § 1716.2 subd. (a)(3)	Record requirements - Compounding for future use - The expiration date of the finished product	$500.00

CONDUCT:

Using Expired Ingredients to Compounded Medication Prohibited. Business and Professions Code section 4169, subsection (a) part 4, Prohibited Acts-Selling Expired Medication, prohibits a pharmacy from purchase, trade, sell, or transfer of a dangerous drug after the beyond use date on label. Hartley Med Ctr Phcy (PHY 20643) failed to comply. Specifically on 10-1-09, Hartley Med Ctr Phcy (PHY 20643) located at 113 W. Victoria Street in Long Beach, 90805 compounded BLT (Benzocaine, Lidocaine, Tetracaine) cream (Lot# BLT-009) using an expired ingredient:

Polysorbate 80	expires 8/09

This is a violation of pharmacy law.

Labeled Expiration Date Exceeds Ingredient Expiration Date. California Code of Regulations section 1716.2 subsections (a) part 3, Record Requirements for Compounding-Expiration Date requires the compounding pharmacy to maintain a record of the expiration date of the finished product. The expiration date can not exceed 180 days or the shortest expiration date of any ingredient use to compound the finished product...Hartley Med Ctr Phcy (PHY 20643) failed to comply. Specifically, on or about 7-31-09, Hartley Med Ctr Phcy (PHY 20643) located at 113 W. Victoria Street in Long Beach, 90805 compounded BLT (Benzocaine, Lidocaine, Tetracaine) cream (Lot# BLT-008) using 3 short dated ingredients that expired before the product's labeled expiration date of 1-31-10.

DMSO	expires 11/09
Polysorbate 80	expires 8/09
Lavender Oil	expires 8/09

This is a violation of pharmacy law.

EXHIBIT "1"

And specifically on 10-1-09, Hartley Med Ctr Phcy (PHY 20643) located at 113 W. Victoria Street in Long Beach, 90805 compounded BLT (Benzocaine, Lidocaine, Tetracaine) cream (Lot# BLT-009) with 2 short date/expired ingredients that expired before the product's labeled expiration date of 4-1-10.

DMSO	expires 11/09
Polysorbate 80	expires 8/09

This is a violation of pharmacy law.

CITATION ISSUED ON: October 04, 2010	TOTAL AMOUNT OF FINE(S): $1,000.00
PAYMENT OF FINE(S) DUE BY: November 03, 2010	

NOV 18 P 3:42

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2010-003639.

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF HARTLEY MED. CTR. PHARMACY INC., REGISTRATION NO. OSP 5641,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and Hartley Med. Ctr. Pharmacy Inc. ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2010-003639 as follows:

1. On July 31, 2006, Respondent Pharmacy became registered by the Board as a non-resident prescription drug outlet in the State of Colorado and was issued Registration No. OSP 5641 ("Colorado Registration").

2. The Board has jurisdiction over Respondent Pharmacy, its Colorado Registration, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2009), otherwise known as the Pharmaceuticals and Pharmacists Act.

3. Respondent Pharmacy's address of record with the Board and current location is 113 W. Victoria St., Long Beach, CA 90805.

4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.

5. On October 30, 2009, Board staff initiated a Complaint against Respondent Pharmacy because it failed to comply with the data submission requirements of Colorado's Electronic Prescription Drug Monitoring Program ("PDMP") for the reporting period(s) of October 16, 2009, through October 25, 2009.

6. Respondent Pharmacy subsequently failed to submit the required data to the PDMP reporting dispensing transactions of controlled substances in the State of Colorado for the reporting period(s) of March 16, 2010, through March 25, 2010, and did not submit a "zero" report indicating no dispensing transactions for said reporting period(s) as required by Board rule.

EXHIBIT "2"

7. Respondent Pharmacy does not contest that the conduct described above constitutes a violation of §§12-22-125(1)(c) and 12-22-708, C.R.S. and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's Colorado Registration pursuant to Board Policy 30-8.

DISPOSITION

$5,000.00 Fine with 10% Surcharge and Terms

8. **Fine with Surcharge.** Respondent Pharmacy accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S. Respondent Pharmacy shall pay a fine of **Five Thousand Dollars and No Cents ($5,000.00).** Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of **Five Thousand, Five Hundred Dollars and No Cents ($5,500.00).** The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

9. **Compliance with PDMP.** At all times Respondent Pharmacy is registered with the Colorado State Board of Pharmacy, it shall comply with the data submission requirements of the PDMP. Respondent Pharmacy understands and acknowledges that future violations of PDMP reporting requirements, including failure to submit a "zero" report in the event of no dispensing transactions in Colorado during the relevant reporting period, shall lead to additional penalties pursuant to Board Policy 30-8.

10. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;

    b. To respond to said formal notice of charges;

    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and

    d. To appeal this Board order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against it to the sanctions imposed herein.

11. **Acknowledgments.** The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

12. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

13. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

14. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

15. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

William A Stuart
Authorized Agent of Respondent Pharmacy

Dated: 5/5/10

Subscribed and sworn to before me in the County of Los Angeles, State of California, this 05 day of May, 2010 by William A. Stuart, in his/her capacity as an authorized agent of Hartley Med. Ctr. Pharmacy Inc.

My commission expires: January 28, 2011

Patrick F. Sullivan
Notary Public

PATRICK F. SULLIVAN
Comm. No. 1721813
NOTARY PUBLIC - CALIFORNIA
LOS ANGELES COUNTY
My Comm. Exp. Jan. 28, 2011

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS 17th DAY OF May, 2010.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, postage prepaid, at Denver, Colorado this 9th day of April 2010, addressed as follows:

Hartley Med. Ctr. Pharmacy Inc.
Attn: William Stuart, RPH
113 W. Victoria St.
Long Beach, CA 90805

John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, postage prepaid, at Denver, Colorado this 18th day of May 2010, addressed as follows:

Hartley Med. Ctr. Pharmacy Inc.
Attn: William Stuart, RPH
113 W. Victoria St.
Long Beach, CA 90805

And by Intradepartmental Mail:

John C. Steele
Settlement Specialist
Office of Expedited Settlement
1560 Broadway, Ste. 880
Denver, CO 80202

Agent of the Board

MAY 18 P 3:31

Hartley Medical Center Pharmacy, LLC

Affiliated Persons – Officers and Directors

The persons listed below are the officers and directors of Hartley Medical Center Pharmacy, LLC.

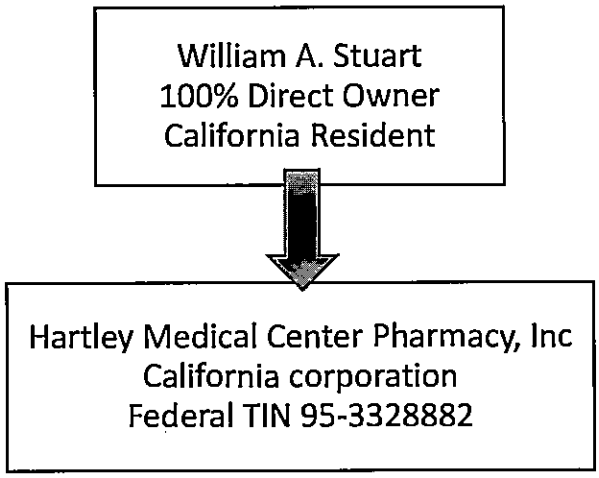
Name	Position/Title	Address
Matthew Deans	President, CEO/Director	[redacted]
Eric Mollman	Treasurer and Director	
Jeffrey Baker	Secretary and Director	

Owner of Hartley Medical Center Pharmacy, LLC is Pentech Holdings, Inc.

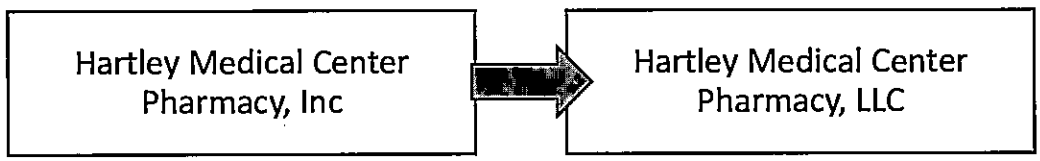
Name	Address	Equity Interest
Pentech Holdings, Inc.	4 Creek Parkway Boothwyn, PA 19061	100.0%

Hartley Medical Center Pharmacy Change of Ownership

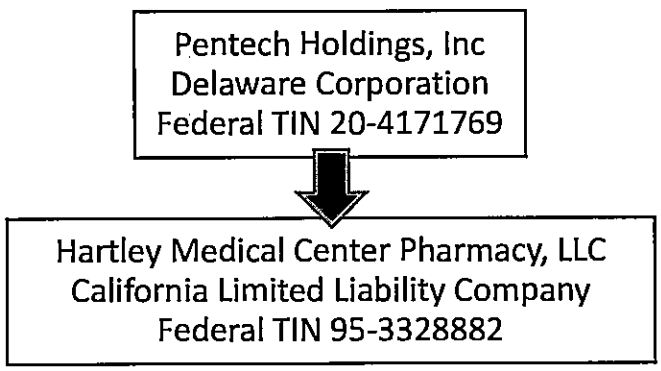
1. Hartley Medical Center Pharmacy Pre-Close Ownership



2. On closing day, Hartley Medical Center, Inc. will undergo a reorganization to Hartley Medical Center, LLC. No change to business operations will occur. No change in Federal TIN.



3. Hartley Medical Center Pharmacy Post-Close Ownership



Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	HARTLEY MEDICAL CENTER PHARMACY, INC.
Entity No.:	0877508
Registration Date:	11/13/1978
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of September 11, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 367304027

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Hartley Medical Center Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable): PH01865

Physical Address: 113 W Victoria Street

City: Long Beach State: CA Zip: 90805

Mailing Address (if different from physical address): 4 Creek Parkway

City: Boothwyn State: PA Zip: 19061

Telephone: 888-671-2888 Website: www.hartleymedical.com

Licensing Company Email: pharmacyregulatory@pentechealth.com

Section 2: Personal Information

First: William Middle: Allan Last: Stuart

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Arizona		05/85	
Address	**City**	**State**	**Zip**
1200 E University Blvd.	Tucson	AZ	85721
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Wilson High School			
Address	**City**	**State**	**Zip**
4400 E. 10th Street	Long Beach	CA	90804
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20-present	[redacted]			
09/19-06/20				
-09/19				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Hartley Medical Center Pharmacy, Inc			10/08-present	
Business Address		City	State	Zip
113 West Victoria Street		Long Beach	CA	90805
Phone	Title		Number of Employed Hours	
562.595.7548	President		34,000	
Description of Duties				
President, Pharmacist in Charge				

Business Name			From - To (MM/YY – MM/YY)	
Hartley Medical Center Pharmacy, Inc			9/85-10/08	
Business Address		City	State	Zip
2888 Long Beach Blvd.		Long Beach	CA	90806
Phone	Title		Number of Employed Hours	
	President		46,000	
Description of Duties				
President, Pharmacist in Charge				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✔	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4/5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/01	10/02	CA	Long Beach	Los Angeles

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
BC 263403	Superior Court

Reason/Charge
My brother sued my for profits from my pharmacy

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Charles Stuart/William Stuart and Hartley Medical Center Pharm	Lawsuit

Name of Business/Industry/Entity
Hartley Medical Center Pharmacy, Inc

Provide explanation below:

William A Stuart

Original Signature (electronic, copies or stamps not accepted)

9-18-25

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/2009	5/2010	CO	Denver	Denver
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2010-003639		Colorado Board of Pharmacy		
Reason/Charge				
Failure to comply with data submission requirements for Colorado's Electronic Prescription Monitoring Program				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Colorado Board of Pharmacy/ Hartley Medical Center Pharmacy		Administrative Proceeding		
Name of Business/Industry/Entity				
Hartley Medical Center Pharmacy				

Provide explanation below:

In a Final Order entered May 17, 2010 the Colorado Board of Pharmacy disciplined Hartley for noncompliance with the Board's prescription drug monitoring program rules. For the periods of October 16, 2009 through October 25, 2009 and March 16,2010 through March 25, 2010 Hartley did not submit a zero report indicating no dispensing of prescriptions for the respective periods. A fine of $5, 500 was paid to the State of Colorado and no further action was taken.

William A Fraser

Original Signature (electronic, copies or stamps not accepted)

9-18-25

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/2010	10/2010	CA	Sacramento	Sacramento
Case # Citation No. CI 2009 41822		**Governing, licensing, Arresting Presiding Body/Agency/Court** California Board of Pharmacy		
Reason/Charge The Board cited Hartley for using an expired ingredient.				
Plaintiff/Defendant/Claimant/Respondent California Board of Pharmacy/Hartley Medical Center Pharmacy			**Lawsuit/Arbitration/Bankruptcy** Administrative Proceeding	
Name of Business/Industry/Entity Hartley Medical Center Pharmacy				

Provide explanation below:

The California Board of Pharmacy cited Hartley for using an expired ingredient to compound a medication. Under California law, this citation is not considered a disciplinary action for reporting purposes. Hartley paid a $1,000 fine.

Original Signature (electronic copies or stamps not accepted)

9-18-25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/18/2015	1/21/2016	HI	Honolulu	Honolulu
Case # PHA 2015-34-L		**Governing, licensing, Arresting Presiding Body/Agency/Court** Hawaii Regulated Industries Compliant Office		
Reason/Charge Failure to report a Colorado Noncompliance violation and a California citation				
Plaintiff/Defendant/Claimant/Respondent Hawaii Board of Pharmacy/Hartley Medical Center Pharmacy			**Lawsuit/Arbitration/Bankruptcy** Administrative Proceeding	
Name of Business/Industry/Entity Hartley Medical Center Pharmacy				

Provide explanation below:

Hartley paid a fine of $1,500 to settle allegations by the Hawaii Regulated Industries Complaint Office that Hartley failed to timely report the 2010 Colorado Noncompliance violation and the 2010 California Citation.

Original Signature (electronic, copies or stamps not accepted)

9-18-25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/2016	12/2016	MI	Lansing	Ingham
Case # 53-16-140779		**Governing, licensing, Arresting Presiding Body/Agency/Court** Michigan Board of Pharmacy		
Reason/Charge The Michigan Board of Pharmacy found Hartley in violation of state law for failing to report disciplines by other states.				
Plaintiff/Defendant/Claimant/Respondent Michigan Board of Pharmacy/ Hartley Medical Center Pharmacy			**Lawsuit/Arbitration/Bankruptcy** Administrative Proceeding	
Name of Business/Industry/Entity Hartley Medical Center Pharmacy				

Provide explanation below:

The Michigan Board of Pharmacy found Hartley in violation of state law which provides for reciprocal disciplinary action based on the 2010 Colorado Noncompliance and the 2010 California Citations. As part of a consent order, Hartley paid a fine of $5,000.

Original Signature (electronic, copies or stamps not accepted)

9-18-25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/2016	8/2017	AL	Montgomery	Montgomery
Case # 16-L-0121		**Governing, licensing, Arresting Presiding Body/Agency/Court** Alabama Board of Pharmacy		
Reason/Charge Disciplinary action brought as a result of an FDA Warning Letter				
Plaintiff/Defendant/Claimant/Respondent Alabama Board of Pharmacy/ Hartley Medical Center Pharmacy			**Lawsuit/Arbitration/Bankruptcy** Alabama Board of Pharmacy	
Name of Business/Industry/Entity Hartley Medical Center Pharmacy				

Provide explanation below:

Hartley reached a settlement agreement with the Alabama Board of Pharmacy to resolve disciplinary actions related to the allegations contained in an FDA Warning Letter. AS part of the agreement, Hartley's Alabama license was placed on probation and Hartley agreed to not renew following expiration of the license.

Original Signature (electronic, copies or stamps not accepted)

9.12.25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
3/2016	6/2016	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2016-296	Colorado Board of Pharmacy

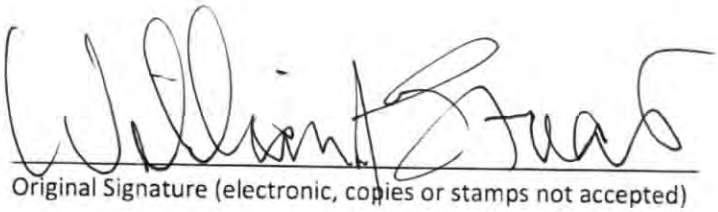
Reason/Charge
Failure to report the 2010 California Citation

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Colorado Board of Pharmacy/Hartley Medical Center Pharmacy	Administrative Proceeding

Name of Business/Industry/Entity
Hartley Medical Center Pharmacy

Provide explanation below:

Hartley paid a fine of $2,300 to settle allegations by the Colorado Board of Pharmacy that Hartley failed to timely report the 2020 California Citation.



Original Signature (electronic, copies or stamps not accepted)

4-18-25

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
8/2017	8/2018	Texas	Austin	Travis County
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
L-17-027	Texas Board of Pharmacy			
Reason/Charge				
Reciprocal Discipline for Alabama				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Texas Board of Pharmacy/Hartley Medical Center Pharmacy	Administrative Proceeding			
Name of Business/Industry/Entity				
Hartley Medical Center Pharmacy				

Provide explanation below:

Hartley and the Texas Board of Pharmacy negotiated an Agreed Board Order to resolve the disciplinary action initiated in response to the action taken by the Alabama Board of Pharmacy. As part of the order, Hartley paid a $5,000 fine and Hartley's license was publicly reprimanded.

Original Signature (electronic, copies or stamps not accepted)

9-18-25
Date

I, William A Stuart, **certify that as the designated representative for**

Hartley Medical Center Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WAS I am at least 21 years of age;
3. WAS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WAS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WAS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WAS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WAS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

William Stuart

Print Name (First, Last)

William Stuart

Original Signature (electronic, copies or stamps not accepted)

9-15-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Stuart

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-18-25

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of LOS ANGELES

I, WILLIAM STUART, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-18-25

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

PLEASE SEE ATTACHED FOR CA GOV'T CODE 8202 COMPLIANT JURAT

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 18th (Date) day of September (Month), 20 25 (Year), by

(1) William Stuart

(and (2) ——→),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

KAYLA CHRISTINE HAGBERY
Notary Public - California
San Bernardino County
Commission # 2459663
My Comm. Expires Aug 17, 2027

Signature _____
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada State Board of Pharmacy

Document Date: 09/18/2025 Number of Pages: Nine

Signer(s) Other Than Named Above: None ——→

©2019 National Notary Association

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Hartley Medical Center Pharmacy, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH01865

Physical Address: 113 W. Victoria Street

City: Long Beach State: CA Zip: 90805

Mailing Address (if different from physical address): 4 Creek Parkway

City: Boothwyn State: PA Zip: 19061

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): 888-671-2888

Fax: 800-648-8550 Contact Email: pharmacyregulatory@pentechealth.com

Website: www.hartleymedical.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): William Stuart

Supervising/Managing Pharmacist NV Pharmacist Registration #: 09062

Name of Designated Person(s) as defined by revised USP-797 guidelines: William Stuart

Email of Designated Person(s): wstuart@hartleymedical.com

Telephone of Designated Person(s): 888-671-2888

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 05/09/2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? weekly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Morphine
fentanyl
sufentanil
hydromorphone
clonidine
bupivacaine
baclofen
ketamine

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL

Address: 840 Research Pkwy #546

City: Oklahoma State: OK Zip: 73104

Telephone: 405-271-1144

13. What is your procedure for visual inspection of compounded sterile products?
Each compounded sterile product (CSP), in its final container-closure system, is visually inspected against both a light and dark background to detect any visible particulate matter, container defects, or evidence of compromise prior to release.

14. How often do you perform glove fingertip and medial fill testing?
monthly

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
All compounding staff are required to complete and pass all didactic and practical training and assessments prior to compounding for human use. Training includes reading USP 797, Compounding Policy and Procedures, three consecutive Aseptic Manipulation Competency Evaluation with Media Fill, post gloved finger tip and surface sampling, three consecutive Garbing and Hand Hygiene Assessment with gloved fingertip sampling, Cleaning and Disinfecting Technique Assessment, receive a 90% or higher on the Compounding Competency Exam, pass sterility potency and endotoxin testing for three CSP compounded for testing purpose only. This training is completed initially and then on an ongoing basis every three months.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
On a daily basis, inside PEC and floors of SEC are cleaned with sterile Vesphene, a phenolic cleaning and disinfecting agent. After the required contact time is observed, sterile 70% IPA is used to remove residue of the disinfectant.

On a weekly basis, the inside and outside surfaces of PEC, and ceilings, walls, and floors of SEC are cleaned with sterile Sporklenz, a one-step sporicidal cleaning and disinfecting agent. After the required contact time is observed, sterile 70% IPA is used to remove residue of the disinfectant.

17. Who performs the sterile compounding process at your facility?

pharmacist and pharmacy technician

18. Who is responsible and accountable for the sterile compounding process at your facility?
Designated person: Mirian Paik

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
CSPs are shipped in validated temperature controlled boxes with ice packs. Ship out instructions are adjusted according to weather and season. Ship out studies are conducted every three months and or during periods of extreme weather. Shipping procedures are modified as needed based on study results.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding:)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Morphine
fentanyl
sufentanil
hydromorphone
clonidine
bupivacaine
baclofen
ketamine

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

every three months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

weekly

5. What is the frequency for completing surface sampling? weekly		
6. What is the frequency for using sporicidal agents? weekly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Stuart

Name of Person who Completed the Form

PIC

Title

Signature (copies or stamps not accepted)

9-18-25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Outsourcing Facility ___ Wholesaler ___ Hypodermic ___

Date: 1/28/2025 Inspector: Manisha Patel

Firm: HARTLEY MEDICAL CENTER PHARMACY INC Phone: (562) 595-7548

Address: 113 W VICTORIA STREET City: LONG BEACH Zip: 90805

Ownership: CORPORATION

Permit #: LSC99011 Permit Exp: 5/1/2025 DEA#: AH8572984 DEA Exp: 10/31/2026

Date of Self Assessment Form: 1/7/2025 Other Permit #: N/A Date of DEA Inventory: 1/17/2025

Hours M-F: 9AM-5:30AM Hours Saturday: CLOSED Hours Sunday: CLOSED

PIC WILLIAM A STUART RPH39665 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
MIRIAN PAIK	RPH78165	CESAR BENAVIDEZ	TCH19035
AMY P TRINH	RPH64432	KATELIN BORJA	TCH18044
VY M NINH	RPH87644	SHERIE MAE MARCE	TCH185155

Inspector Remarks:

Licensed Sterile Compounding Renewal Inspection

PIC: William Stuart

- email: wstuart@hartleymedical.com
- phone: (562) 505 6523

In advance of the onsite inspection, documents were sent via e-mail by RPH Mirian Paik. An onsite inspection was performed on 01/28/2025 with the assistance of RPH Paik, Director of Pharmacy. Licensed in 49 states (exception is Alabama).

General Information:

- Description: A closed door pharmacy. Currently compound intrathecal products, primarily pain management medications and 1 non-sterile product (diltiazem).
- Sterile compounding:
  - Non-hazardous, Category 2-3; all patient specific
    - Average non-hazardous CSPs per day: 150
    - Designated person: RPH Paik
- Non-sterile compounding:
  - Types of compounds: Diltiazem HCl 2% in Surgilube topical rectal gel
    - Average non-HD CNSP: ~1-2/week
- Off-site record storage waiver: not in use at this time
- PIC and facility receiving BOP subscriber alerts
- Courier: FedEx and subsidiary of UPS, Roadie
- Wholesaler: Amerisource Bergen/Smart Source, McKesson, Piramal

INSPECTION REPORT

- Reverse distributor: Triumvirate Environmental Services
- Waste: Precision Biowaste

According to documents and statements provided by PIC:

- No changes to the physical layout of the sterile compounding facility in the past 12 months
- No changes to the sterile compounding equipment in the past 12 months
- No recalls related to CSPs in the past 12 months
- No adverse events related to pharmacy's CSPs from the past 12 months
- No FDA, DEA, or accreditation inspections in last 12 months
- NABP surveyor on 1/22/25
- No changes in types of sterile products compounded in the past 12 months
- No changes to list of sterile medications compounded in the past 12 months

Posted:

- Original license with renewal
- DEA registration
- Notice to Consumer and Interpretive Services

Compounding Area: Modular Compounding Area

- Gowning room (ISO 8) → Anteroom (ISO 7) → Buffer Room (ISO 7)
- Gowning room: sink on clean side of demarcation, 2 steel supply carts (primarily PPE)
- Anteroom: 1 steel movable cart between ISO 7 areas, a pass-through window to unclassified area and a pass-through window to the buffer room; steel cabinet for quarantined products, printer, 1 wired rack for glass flasks/beakers
- Buffer Room: 1 powder hood (particle counter is on during the weighing of ingredients per RPh Paik), 5 laminar flow hoods, large steel island (workstation)

Certification: Last completed on 11/15/24 by TSS

- PECs certified
- Non-viable air sampling performed
- HEPA filters leak test passed
- ACPH (HVAC and PEC documented separately – non-HD buffer room)
- Viable air and surface sampling performed
- Calibrations: Temperature/Humidity Gauge/Magnehelic/Incubator/Autoclave/pH meter
- October 11, 2024: Video of smoke studies reviewed onsite

Items Reviewed:

- Previous inspection
- Compounding and Pharmacy/Hospital Self-Assessments
- Master formula, compounding log, label examples
- Following reviewed:
    - Sterile compounding balance, pH meter and repeater pumps calibration logs
    - Setra continually monitoring system
    - Room, refrigerator, incubator temperature logs (continually monitored and manually logged daily)
    - Differential pressure logs (manually logged daily)
    - Humidity logs (Setra)
    - Dry heat pyrogenation (glassware and equipment), ECV annually

INSPECTION REPORT

- Particle count monitored continuously during compounding
- Cleaning logs, daily/monthly, rooms/hoods
    - Agents used in addition to sterile water: sterile IPA 70%, Vesphene, SporKlenz
- QA: End-product testing performed - sterility, potency and endotoxin, filter integrity testing for all batches; patient specific products are assigned a BUD of 10 days because does not undergo testing
- In-house surface sampling, active air sampling completed after each batch
- Surface sampling and active air samples are tested weekly
- If outside limit, then sample is sent for identification (species level) to US Micro
- Rapid sterility method Celsis for sterility - ARL

Items Observed:

- Visual inspection of compounding areas and hoods
    - RPH Ninh compounding and RPH Trinh verification of final product in buffer room
- Staff garbing and gowning, observed TCH Benavidez
    - lint free towels, nail picks, and alcohol-based hand rub available
- Drug storage
- Pressure differentials between rooms
- Room, refrigerator, incubator temperatures, continuously monitored
- Humidity, continuously monitored
- Hot/cold running water
- Eye wash area
- Dedicated cleaning supplies
- Non-sterile compounding area

Policies and Procedures Reviewed:

- Annual review of SOPs - last annual review 1/8/2025 by PIC and Designated person (RPH Paik)
- Reviewed Sterilization and Depyrogeation
- Release Testing
- Personnel Training and Evaluation

Training: Viewed for RPH and TCH

- Read Sterile Compounding P&P
- USP 797
- Aseptic Manipulation Competency Evaluation with Media Fill
- Garbing and Hand Hygiene Assessment with GFT
- Cleaning and Disinfecting Technique Assessment
- Misc. Compounding Related Practices
- Compounding Competency Exam
- Personnel Process Compounding Sterile Preparation Validation End Product Testing
- Environment Monitoring
- Steam Sterilization Assessment
- Dry Heat Sterilization and Depyrogenation Assessment
- Needle Stick Prevention Guideline and Acknowledgement

Discussion/Education:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

- **Please note** the board may be in further communication with the facility post inspection.
- A PDF of the 2024 law book is available online at the Board's website: https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf
- The May 2024 issue of The Script is available online. It includes information related to reproductive/gender affirming care, pharmacy mobile units, new CE requirements for pharmacists and technicians, and FAQs related to epinephrine standing orders. The December 2024 issue of The Script is also available online. Previous issues also are available in the newsletter archive.
- Send notification of all recalls, ADRs, and complaints to: compounding.report@dca.ca.gov
- November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards. The statement is available on the BOP website: https://www.pharmacy.ca.gov/about/compounding_policy.pdf
The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters. During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the BOP website: https://pharmacy.ca.gov/meetings/agendas/2023/23_apr_bd_mat_xiv.pdf
Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA: https://www.dir.ca.gov/dosh/lawsandregulations.htm
Educational Links and References:
1. Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
   BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
   BUD Reference for the 2021 Proposed Revisions to <795>
   BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
   BUD Reference for the 2021 Proposed Revisions to <797>
2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
   https://www.fda.gov/media/94155/download
3. FDA Drug Establishments Current Registration Site: https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
4. FDA to Compounders: Know Your Bulks and Excipients Suppliers:
https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Mirian Park

Inspector (sign) _____

Inspector (print) MANISHA PATEL

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 20643

NAME: HARTLEY MED CTR PHCY INC

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

113 W VICTORIA STREET
LONG BEACH CA 90805
LOS ANGELES COUNTY

ISSUANCE DATE

MAY 1, 1979

EXPIRATION DATE

MAY 1, 2026

CURRENT DATE / TIME

AUGUST 12, 2025
11:59:48 AM

LICENSE RELATIONSHIPS

NAME: HARTLEY MEDICAL CENTER PHARMACY INC

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 99011 **PRIMARY STATUS:** CLEAR

ADDRESS :
113 W VICTORIA STREET
LONG BEACH CA 90805
LOS ANGELES COUNTY

NAME: STUART, WILLIAM A

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 39665 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY

LICENSING DETAILS FOR: LSC 99011

NAME: HARTLEY MEDICAL CENTER PHARMACY INC

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

113 W VICTORIA STREET
LONG BEACH CA 90805
LOS ANGELES COUNTY

ISSUANCE DATE

JULY 1, 2003

EXPIRATION DATE

MAY 1, 2026

CURRENT DATE / TIME

AUGUST 12, 2025
12:1:41 PM

LICENSE RELATIONSHIPS

NAME: HARTLEY MED CTR PHCY INC

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 20643 **PRIMARY STATUS:** CLEAR

ADDRESS :
113 W VICTORIA STREET
LONG BEACH CA 90805
LOS ANGELES COUNTY

VOID VOID VOID

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AH8572984	10-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-13-2023

HARTLEY MEDICAL CENTER PHARMACY
HARTLEY MEDICAL CENTER PHARMACY
113 W VICTORIA ST
LONG BEACH, CA 908052162

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AH8572984	10-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-13-2023

HARTLEY MEDICAL CENTER PHARMACY
HARTLEY MEDICAL CENTER PHARMACY
113 W VICTORIA ST
LONG BEACH, CA 908052162

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

21.3 Employee Training for Compounded Nonsterile Preparations

Drafted by: William Stuart	**Date Effective: Jun. 2021**
Edited by: Mirian Paik	**Date Reviewed: Jun. 2021**
Approved by: Mirian Paik	**Date Revised: Nov. 2024**

PURPOSE:

To provide an appropriate orientation and training program for all staff prior to assuming patient care and compounding responsibilities. To provide ongoing education to all staff to ensure a current knowledge base for providing quality patient care.

POLICY:

1. All personnel involved in compounding and checking CNSP must undergo initial training prior to preparing such CNSP, then subsequently annually to maintain competency.
2. The CNSP training is to be completed prior to compounding any products to be dispensed.
3. All personnel involved in CNSP must demonstrate ability to understand and interpret of SDS by completing the SOP Personnel Competency Exam – Compounded Nonsterile Preparation with passing scores.
4. Personnel will observed at random to ensure adherence to policies and procedures. Any deficient practices will be documented and corrective action taken. Observation and any corrective action will be documented on Attachment I

PROCEDURE:

1. Prior to compounding, all personnel will receive a copy of the USP Chapter <795> Pharmaceutical Compounding: Non-Sterile Preparations.
2. All personnel will read and adhere to the Hartley Medical Center Pharmacy Policy and Procedures. If the employee has any questions regarding policies and selected reading, it is the employee's responsibility to discuss these issues with their immediate supervisor.
3. All personnel involved with the production or checking of non-sterile products will participate in a general orientation as part of the training. Orientation will consist of several steps with the employee showing a level of competency at each step before progressing to the next.
    a. Review and comprehension of prescriptions that require compounding.
    b. Introduction to medication, equipment, and tools used in compounding.
    c. Introduction to appropriate hand hygiene, gowning, and gloving.
    d. Trainee is to observe a demonstration of the compounding procedure.
    e. Trainee will perform the procedures under supervision successfully prior to compounding independently.

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f. Trainee will demonstrate ability to handle equipment involved as well as troubleshooting process.

4. After reading policies and procedures, each stage of the compounding process will be physically reviewed with the supervisor.
5. As each task is completed during training and validation, the Employee-Training Log (Attachment I and Attachment II) is to be dated and signed by both the trainee and supervisor and filed appropriately.
6. Personnel who compound and/or have direct oversight of compounding will participate in competency exams and/or continuing education programs every 12 months to maintain skills necessary to do their respective jobs.
7. Each employee will perform a "Non-Sterile Compounding Assessment" (Attachment I) and "Non-Sterile Compounding Equipment Assessment" (Attachment II) with a supervisor or pharmacist.

21.3 Attachment I: Compounded Nonsterile Preparation Assessment Form

Employee Name/Title: _____ **Date:** _____

Tasks	Pass	Fail
1. Conducts correct calculations on compounding record.		
2. Stages appropriate ingredients using proper technique.		
3. Positions objects within the compounding area where nothing interrupts compounding process.		
4. Conducts all manipulations to prevent contamination.		
5. Properly dissolves / levigate active pharmaceutical ingredients and excipients.		
6. Manipulates spatulas properly.		
7. Programs unguator for intended topical preparation.		
8. Accurately weighs pharmaceutical ingredients within containment hood.		
9. Utilizes appropriate packaging.		
10. Does not touch or contaminate any component used in preparation compounding.		
11. Assess compounding consistency to ensure elegant mixing.		
12. Properly documents compounding records where required.		
13. Completes Non-Sterile Competency Exam		
14. (Initial Training Only) Observes demonstration of compounding prior to performing procedures		
Random Observation Only. Note/Corrective Action Taken		

Employee Signature: _____ Date: _____

Supervisor Signature: _____ Date: _____

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21.3 Attachment II: Compounded Nonsterile Preparation Equipment Assessment Form

Employee Name/Title: _____ **Date:** _____

Tasks	Pass	Fail
Wipes down Unguator and appropriate parts prior to use		
Selects appropriate size jar and blade for the Unguator		
Selects appropriate mix-setting and volume		
Mount the mixing unit and check to see the mixing looks smooth and consistent		
Reduce air and firmly screw on jar cap		
Understands troubleshooting/Error Messages SAMIX U100 cannot be switched on : Check secure and active power supply "Mixing engine overload" message: device is overloaded. Press "OK". Wait 30 minutes and re-start "Mixer not fixed!": Press "OK" and mount the mixing tool again so that the mixing blade shaft engages in the bayonet mount "Jar not fixed": Press "OK" and mount the mixing unit properly so that the mixing blade shaft engages in the bayonet mount		
Wipes down Unguator and appropriate parts prior to use		

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21.4 Employee Training for Compounded Nonsterile Preparation – Safety Data Sheet

Drafted by: Mirian Paik | **Date Effective: Nov. 2024**
Approved by: Mirian Paik | **Date Revised:**

Purpose

To ensure all personnel involved in CNSP can understand and interpret Safety Data Sheets (SDS) for components used in non-sterile compounding. requires familiarity with the handling, storage, and safety protocols for each component used in non-sterile preparations.

Policy

1. All personnel involved in CNSP must undergo initial training then subsequently annual training on this SOP (Attachment I). Training must be documented (Attachment II)
2. All personnel involved in CNSP must demonstrate ability to understand and interpret of SDS by completing the SOP Personnel Competency Exam – Compounded Nonsterile Preparation with passing scores
3. All personnel involved in CNSP must be able to locate and access SDS

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Attachment I: SDS Training

Objective: To provide personnel with the knowledge and skills needed to read, understand, and use Safety Data Sheets (SDS) to ensure safe handling, storage, and disposal of hazardous materials.

Overview of SDS and Its Importance

- What is an SDS?

A document provided by manufacturers that details information about chemical products, including hazards, handling, storage, and emergency measures.

- Why does SDS Matter?

SDSs help identify and manage risks related to hazardous materials, enabling healthcare workers to protect themselves and others.

SDS Structure and Key Sections

- Identification: Name of the substance or mixture and details about its manufacturer.
  - Importance: Helps in quickly identifying the product and understanding its use or purpose.
- Hazard Identification: Identifies the potential hazards (e.g., health, physical, environmental) of the substance.
  - Importance: Helps workers recognize if a product is flammable, toxic, corrosive, etc., which guides them in handling and storage.
- Composition/Information on Ingredients: Lists chemical ingredients and their concentrations.
  - Importance: Aids in understanding specific chemical risks, particularly if multiple chemicals are used in the workplace.
- First-Aid Measures: Details on what to do if someone is exposed to the chemical.
  - Importance: Provides essential steps for responding to accidental exposure and minimizing harm.
- Fire-Fighting Measures: Instructions for dealing with fires caused by the chemical, including suitable extinguishing agents.
  - Importance: Reduces fire risk by identifying how to safely extinguish a chemical-related fire.
- Accidental Release Measures: Procedures for safely cleaning up spills and leaks.
  - Importance: Prevents the spread of hazardous substances and minimizes exposure risk.
- Handling and Storage: Guidelines for safe handling and storage practices.
  - Importance: Helps prevent accidents, contamination, or degradation of chemicals.

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- Exposure Controls/Personal Protection (PPE: Lists recommended protective equipment and exposure limits.
  - ➢ Importance: Ensures workers use the correct PPE to minimize exposure risk.
- Stability and Reactivity: Information on chemical stability and potential reactions.
  - ➢ Importance: Prevents accidental reactions that could release toxic substances or cause explosions.
- Disposal Considerations: Proper disposal methods for the chemical.
  - ➢ Importance: Ensures chemicals are disposed of legally and safely to avoid environmental contamination.

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Acknowledgement of Training

Date of Attendance: _____

Training : Safety Data Sheet

I confirm that I attended the training listed above. I listened, read, and understood the training, and I understand that as an employee, it is my responsibility to abide by **Hartley Medical's** *policy and procedures, in accordance with the training and laws set forth.*

I confirm that the following document(s) were given to me; SOP Employee Training for Compounded Nonsterile Preparation – Safety Data Sheet Attachment I SDS Training Material

If I have questions about the training, materials presented or **Hartley Medical's** *policy and procedures, I understand it is my responsibility to seek clarification from the Human Resources Department.*

Employee Name (Print)_____

Employee Signature_____ **Date**_____

21.5 Employee Training for Compounded Nonsterile Preparations- Component Spill and Disposal

Drafted by: Mirian Paik **Date Effective: Nov. 2024**

Approved by: Mirian Paik **Date Revised:**

Purpose

To establish safe and consistent procedures for handling, cleaning, and disposing of spilled components used in non-sterile compounding, in compliance with USP 795 guidelines.

Materials

- Disposable gloves (nitrile or latex-free)
- Eye protection (goggles or face shield)
- Respiratory protection (if needed, based on component type)
- Spill kit (absorbent pads, absorbent powders, disposable wipes)
- Biohazard or hazardous waste disposal bags (if applicable)
- Disinfectant solution appropriate for the material

Policy

4. All personnel involved in CNSP must undergo initial training then subsequently annual training on this SOP. Training must be documented (Attachment I)
5. All personnel involved in CNSP must demonstrate understanding of spill management and disposal procedures by completing the SOP Personnel Competency Exam – Compounded Nonsterile Preparation with passing scores
6. The Director of Pharmacy or a pharmacist on staff must be notified as soon as practical
7. Spill must be documented on the Spill and Disposal Log (Attachment II)

Procedure

In the event of a spill follow the following procedures

1. Stop Work and Secure Area
    a. Pause any compounding activities and secure the area where the spill occurred to prevent contamination spread.
    b. Inform the supervising pharmacist of the spill.
2. Contain the Spill

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a. Don appropriate PPE before handling the spill.
b. Use Spill Kit
    i. Apply absorbent materials to contain the spill
    ii. Use wipes or absorbent powder to clean up the spilled component
    iii. Place all contaminated cleanup materials in hazardous waste or biohazard bags as appropriate.

3. Cleanup Procedures
    a. Carefully gather and contain the spilled material using the spill kit's absorbent pads and other materials.
    b. Place contaminated absorbents in designated biohazard or hazardous waste disposal bags.
    c. Wipe the affected area with appropriate disinfectant to eliminate residues.
    d. Dispose of used PPE and any other contaminated cleanup materials according to hazardous or non-hazardous waste and other required regulatory guidelines.
    e. Sanitize hands and any exposed skin after removing PPE.
4. Document the incident in the Spill and Disposal Log (Attachment II)
    a. Submit the completed document to the Director of Pharmacy for review.
    b. Reviewed document will be filed appropriately.

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Acknowledgement of Training

Date of Attendance: _____

Training : Component Spill and Disposal

I confirm that I attended the training listed above. I listened, read, and understood the training, and I understand that as an employee, it is my responsibility to abide by **Hartley Medical's** *policy and procedures, in accordance with the training and laws set forth.*

I confirm that the following document(s) were given to me; SOP Employee Training for Compounded Nonsterile Preparations - Component Spill and Disposal

If I have questions about the training, materials presented or **Hartley Medical's** *policy and procedures, I understand it is my responsibility to seek clarification from the Human Resources Department.*

Employee Name (Print)_____

Employee Signature_____ **Date**_____

Attachment II: Spill and Disposal Log

Date/Time of Spill: _____ **Location:** _____

Component Spilled: _____ **Quantity Spilled:** _____

Description of Incident:

Immediate Action Taken:

PPE Utilized:

Disposal Method:

Completed By: _____

Witness/Others involved (if applicable): _____

Notes/Follow Up Actions:

Signature/Date

_____ _____

Completed personal Director of Pharmacy

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21.6 Employee Training for Compounded Preparation – Interpretation and Review of Certificates of Analysis (COA)

Purpose

To establish a standardized procedure for personnel responsible for the procurement, receipt, and utilization of bulk substances in sterile and non-sterile compounding. This procedure ensures proper review and interpretation of Certificates of Analysis (COAs) to verify compliance with USP <795> and <797> standards and to confirm the suitability of bulk substances for compounding purposes.

Procedure

1. Receipt of Bulk Substance
    a. Verify that each bulk substance received is accompanied by a COA.
    b. Record the receipt of the COA and corresponding bulk substance in the appropriate log.
2. Initial Review of COA
    a. Verify that the COA includes the following essential elements:
        i. Substance name and CAS number
        ii. Manufacturer/supplier details
        iii. Lot or batch number
        iv. Date of manufacture and expiration date
        v. Specification standards (e.g., USP, EP, BP)
        vi. Results for identity, assay, and purity testing
        vii. Impurity profiles, including heavy metals and residual solvents (if applicable).
3. Detailed Evaluation of COA
    a. Confirm that the test results meet the required specifications and are within acceptable ranges.
    b. Ensure the COA references testing methods compliant with USP or other recognized standards.
4. Approval or Rejection
    a. Approve the bulk substance if:
        i. All required information is present and accurate.
        ii. Test results meet specifications.
    b. Reject the bulk substance if:
        i. The COA is missing critical information.
        ii. Results fall outside acceptable limits.
        iii. The COA lacks documentation of compliance with recognized standards.
    c. If COA is rejected, document in the COA review log.
5. Documentation
    a. Retain a copy of the COA in the Bulk Substance COA File.

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b. Record the following information in the COA Review Log:

6. Training
    a. All personnel must receive training on this SOP before performing COA reviews annually, Attachment I: Understanding and Interpreting Certificates of Analysis (COA) Training.
    b. All personnel must complete an acknowledgement of training form, Attachment II.
    c. All personnel must pass the assessment, Attachment III: Understanding and Interpreting Certificates of Analysis (COA) Assessment

Attachment I: Understanding and Interpreting Certificates of Analysis (COA) Training

Objective: To equip personnel with the knowledge and skills to effectively interpret Certificates of Analysis for bulk substances used in non-sterile compounding, in compliance with USP <795> and <797>.

1. Introduction

A Certificate of Analysis (COA) is a critical document provided by the manufacturer or supplier of bulk substances. It confirms the identity, purity, quality, and compliance of a substance. Proper interpretation of COAs is essential for ensuring the safety and efficacy of compounded preparations.

2. Purpose of a COA
    a. Verifies that a substance meets required standards for use in compounding.
    b. Ensures compliance with regulatory guidelines, such as USP <795> and <797>.
    c. Provides assurance of quality, purity, and potency.
3. Key Components of a COA
    a. Identity Information
        i. Substance Name: Ensure it matches the name in the formulation record.
        ii. CAS Number: Confirms the unique chemical identity of the substance.
        iii. Lot/Batch Number: Tracks the specific batch of the substance.
    b. Manufacturer/Supplier Information
        i. Name, address, and contact details of the manufacturer or supplier
    c. Specifications
        i. Assay or Purity: Percentage purity or assay range.
        ii. Impurities: Levels of heavy metals, residual solvents, and other contaminants.
        iii. Moisture Content: If applicable, especially for hygroscopic substances.
    d. Test Methods and Standards
        i. Reference to testing methods (e.g., USP, BP, or EP standards).
        ii. Acceptable limits for each specification.
    e. Storage and Handling
        i. Specific conditions (e.g., "Store at 25°C, protect from light").
4. Steps to Interpret a COA
    a. Initial Review
        i. Verify the document's authenticity (e.g., official letterhead, supplier details).
        ii. Check that the COA corresponds to the correct lot or batch.
    b. Detailed Evaluation
        i. Cross-check the identity information with the pharmacy's purchase records.
        ii. Confirm that assay and purity values fall within acceptable ranges for the intended use.

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iii. Review impurity profiles for compliance with pharmacopeial limits.
iv. Verify storage conditions and ensure compliance during storage.

c. Final Approval or Rejection
   i. Approve the substance only if all specifications meet required standards.
   ii. Document any reasons for rejection and inform the supplier.

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Acknowledgement of Training

Date of Attendance: _____

Training : Understanding and Interpreting Certificates of Analysis (COA)

I confirm that I attended the training listed above. I listened, read, and understood the training, and I understand that as an employee, it is my responsibility to abide by **Hartley Medical's** *policy and procedures, in accordance with the training and laws set forth.*

I confirm that the following document(s) were given to me; SOP Employee Training for Compounded Preparation – Certificate of Analysis

If I have questions about the training, materials presented or **Hartley Medical's** *policy and procedures, I understand it is my responsibility to seek clarification from the Human Resources Department.*

Employee Name (Print)_____

Employee Signature_____ **Date**_____

Attachment III: Understanding and Interpreting Certificates of Analysis (COA) Assessment

	Pass	Fail
Verify the document's authenticity		
Check that the COA corresponds to the correct lot or batch		
Identify key components		
Confirm that assay and purity values fall within acceptable ranges		
Understands when to approve or reject COA		
Understands maintaining record and documentation of COA review		

Quiz

1. What is the purpose of a COA?

2. List three critical pieces of information found on a COA.

3. A substance can be approved if the COA is missing lot or batch number? T/F

4. A substance can be approved if the assay/purity is outside the acceptable range? T/F

Pharmacy Name:	Hartley Medical Center Pharmacy
Pharmacy Address:	113 West Victoria Street Long Beach CA 90805
NABP Business e-Profile ID:	623495
VPP Inspection Date(s):	01/21/2025;01/22/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	35	3.0	Hartley Medical has a training program in compliance with current USP <795> standards. SOPs related to training were submitted to NABP, including Employee Training for Non-Sterile Products (21.3) and Staff Proficiency Testing – Non-Sterile (21.4. All compounding personnel, including pharmacists and technicians, are trained and qualified per SOP before independently compounding patient-specific CNSPs. During the inspection, the inspector reviewed initial training documentation implemented since the updated USP <795> standards took effect, as well as the most recent CNSP training records. It was noted that initial training did not include COA review training, however, was included in the most recent CNSP training dated November 2024, which was reviewed by the inspector on-site. See attached.	Current	Y	21.3 Employee Training for Compounded Nonsterile Preparations, 21.4 Employee Training for Compounded Nonsterile Preparations – Safety Data Sheet, 21.5 Employee Training for Compounded Nonsterile Preparations – Component Spill and Disposal, 21.6 Employee Training for Compounded Nonsterile Preparations – Interpretation and Review of Certificates of Analysis (COA), 112024 AT Annual CNSP Employee Validation
Clarification or Further Explanation	35	3.1	Hartley Medical has a training program in compliance with current USP <795> standards. SOPs related to training were submitted to NABP, including Employee Training for Non-Sterile Products (21.3) and Staff Proficiency Testing – Non-Sterile (21.4. All compounding personnel, including pharmacists and technicians, are trained and qualified per SOP before independently compounding patient-specific CNSPs. During the inspection, the inspector reviewed initial training documentation implemented since the updated USP <795> standards took effect, as well as the most recent CNSP training records. It was noted that initial training did not include COA review training, however, was included in the most recent CNSP training dated November 2024, which was reviewed by the inspector on-site. See attached.	Current	Y	21.3 Employee Training for Compounded Nonsterile Preparations, 21.4 Employee Training for Compounded Nonsterile Preparations – Safety Data Sheet, 21.5 Employee Training for Compounded Nonsterile Preparations – Component Spill and Disposal, 21.6 Employee Training for Compounded Nonsterile Preparations – Interpretation and Review of Certificates of Analysis (COA), 112024 AT Annual CNSP Employee Validation
Clarification or Further Explanation	35	3.2	Hartley Medical has a training program in compliance with current USP <795> standards. SOPs related to training were submitted to NABP, including Employee Training for Non-Sterile Products (21.3) and Staff Proficiency Testing – Non-Sterile (21.4. All compounding personnel, including pharmacists and technicians, are trained and qualified per SOP before independently compounding patient-specific CNSPs. During the inspection, the inspector reviewed initial training documentation implemented since the updated USP <795> standards took effect, as well as the most recent CNSP training records. It was noted that initial training did not include COA review training, however, was included in the most recent CNSP training dated November 2024, which was reviewed by the inspector on-site. See attached.	Current	Y	21.3 Employee Training for Compounded Nonsterile Preparations, 21.4 Employee Training for Compounded Nonsterile Preparations – Safety Data Sheet, 21.5 Employee Training for Compounded Nonsterile Preparations – Component Spill and Disposal, 21.6 Employee Training for Compounded Nonsterile Preparations – Interpretation and Review of Certificates of Analysis (COA), 112024 AT Annual CNSP Employee Validation

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name:	Hartley Medical Center Pharmacy
Pharmacy Address:	113 West Victoria Street Long Beach CA 90805
NABP Business e-Profile ID:	623495
VPP Inspection Date(s):	01/21/2025;01/22/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	50	29.0	A compounding record is completed for each CNSP compounded pursuant to a patient-specific prescription and was reviewed by the inspector. As noted in section 29.2, the inspector identified that the dosage form was not included in the compounding record (CR). This deficiency has been addressed.	Current	N	
Updates/New SOPs or P&Ps	50	29.2	The compounding record (CR) template has been updated to include the dosage form, Rectal Gel. See attached.	Current	Y	Diltiazem2% surg v3
Clarification or Further Explanation	14	71.00	Data loggers are sent out quarterly not semi annually	Current	N	
Clarification or Further Explanation	25	47.07	Pharmacy has a contract with LS Pedia which provides support for DSCSA. All facets of transaction history is checked to include FDA Wholesale Distributor Database. Pharmacist reviews history when received.	Current	N	
Clarification or Further Explanation	30	93.00	To clarify: patients do not receive their medication from the pharmacy. All prescribers are contacted regularly to discuss any issues that may arise. HM regularly makes adjustments based on prescirbers' feedback.	Current	N	

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Annual CNSP Employee Validation

Employee Name: Amy Trinh Date Initiated: 11/15/24

	Pass	Fail	Date of Assessment
Read HM Sterile Compounding Policies and Procedures	✓		11/15/24
Read USP <795>	✓		
Compounded Nonsterile Preparation Assessment Form	✓		
Compounded Nonsterile Preparation Equipment Assessment Form	✓		
Safety Data Sheet Training Acknowledgement	✓		
Component Spill and Disposal Training Acknowledgement	✓		
Compounded Nonsterile Preperation Competency Exam	✓		
Understanding & Interpreting CoA	✓		

Employee Signature: [signature] Date: 11/15/24

Supervisor Signature: [signature] Date: 11/15/24

EMPLOYEE NON-STERILE COMPOUNDING ASSESSMENT FORM

Employee Name/Title: Amy Trinh / rph **Date:** 11/15/24
Observer: Mirian Park

Tasks	Pass	Fail
1. Performs proper hand washing, gowning and gloving procedures.	✓	
2. Properly cleans the dedicated compounding area before compounding.	✓	
3. Conducts correct calculations on compounding record.	✓	
4. Stages appropriate ingredients using proper technique.	✓	
5. Positions objects within the compounding area where nothing interrupts compounding process.	✓	
6. Conducts all manipulations to prevent contamination.	✓	
7. Properly dissolves / levigate active pharmaceutical ingredients and excipients.	✓	
8. Manipulates spatulas properly.	✓	
9. Programs unguator for intended topical preparation.	✓	
10. Accurately weighs pharmaceutical ingredients within containment hood.	✓	
11. Utilizes appropriate packaging.	✓	
12. Does not touch or contaminate any component used in preparation compounding.	✓	
13. Assess compounding consistency to ensure elegant mixing.	✓	
14. Properly documents compounding records where required.	✓	
15. Completes Non-Sterile Competency Exam	✓	
16. (Initial Training Only) Observes demonstration of compounding prior to performing procedures	—	—
Random Observation Only. Note/Corrective Action Taken		

Employee Signature: [signature] Date: 11/15/24

Supervisor Signature: [signature] Date: 11/15/24

Employee Non-Sterile Compounding Equipment Assessment Form

Employee Name/Title: Amy Trinh /cph **Date:** 11/15/24

Task	Pass	Fail
Wipes down Unguator and appropriate parts prior to use	✓	
Selects appropriate size jar and blade for the Unguator	✓	
Selects appropriate mix-setting and volume	✓	
Mount the mixing unit at the oscillation arm	✓	
Remove mixing unit and check to see the mixing looks smooth and consistent	✓	
Reduce air and firmly screw on jar cap	✓	
Understands Troubleshooting/ Error Messages SAMIX U100 cannot be switched on: check secure and active power supply "Mixing engine overload" message: device is overloaded. Press "OK". Wait 30 minutes and re-start "Mixer not fixed!": Press "OK" and mount the mixing tool again so that the mixing blade shaft engages in the bayonet mount "Jar not fixed": Press "OK" and mount the mixing unit properly so that the mixing blade shaft engages in the bayonet mount	✓	
Wipes down Unguator and appropriate parts prior to use	✓	

Non Sterile Competency Examination

1. The optimal room temperature is: 55°F 72°F 80°F 92°F
2. Compounding can occur when the humidity is 65%. True False
3. Hands should be washed before non-sterile compounding. True False
4. Gloves are required for preparing topical / non-sterile preparations. True False
5. The analytical balance should be turned on ___ minutes before use?

   10 20 30 60
6. The maximum weight the Ohaus analytical balance can weigh?
   100g 220g 310g 500g
7. The maximum weight the Denver analytical balance can weigh?
   5g 51g 310g 610g
8. 7.2 mg of Gabapentin be weighed accurately? True False
9. The steel spatula used for weighing powders should be cleaned with alcohol every?

   Each weighing Daily Every Hour Never
10. Gloves need to be cleaned with alcohol prior to obtaining weighing paper?

    True False

Compounding Procedures
Calculate the following:

11. You need 2% Salcylic Acid in Betamethasone Dipropionate 100 grams. How many grams of Salcylic Acid will you need?

    1g 2g 50g 200g

12. You need 10% LCD in 240 grams of Eucerin. How many milliliters will you draw up of LCD?

2.4mL 10.8mL (24mL) 44mL

13. Compound the Following:

Ketamine 10%
Bupivacaine 2.5%
Ketoprofen 5%
Gabapentin 2.5%
In Pluronic Gel

Quantity: 120gm

DRUG	Units (g)
Ketamine HCl	12
Bupivacaine HCl	3
Ketoprofen	6
Gabapentin	3
Ethoxy Diglycol	
Lip Oil	
Pluronic Gel 20%	QS 120

Ketamine g : $10 \times \frac{120}{100} = 12\ g$

Bupivacaine : $2.5 \times \frac{120}{100} = 3\ g$

Ketoprofen : $5 \times \frac{120}{100} = 6\ g$

Gabapentin : $2.5 \times \frac{120}{100} = 3\ g$

Calculations:

14. What is the primary purpose of an SDS

a) To provide pricing information on chemical products
(b) To detail chemical hazards, handling, storage, and emergency procedures
c) To provide customer reviews of the product
d) To offer instructions for manufacturing the chemical

15. Select the appropriate answer from the options below

First-Aid Measures Disposal Considerations Exposure Controls/Personal Protection

a) Where on an SDS can workers find recommended PPE and exposure limits for safe handling? Exposure Controls / personal protection

b) Which section would you refer to for proper disposal methods for a chemical

Disposal Considerations

c) In which SDS section would you find instructions on what to do if a person is exposed to the chemical

First-Aid Measures protection

16. Which of the following is the correct order of procedures after a spill?

(a) Stop work, contain the spill, clean up, document

b) Clean up, document, contain the spill, stop work

c) Document, stop work, clean up, contain the spill

d) Contain the spill, clean up, stop work, document

END OF TEST

Employee Name: Amy Trinh

Employee Signature: [signature]

Test Graded / Reviewed by: [signature]

Score: 100% **PASS** / **FAIL**

hartleymedical
Serving the Standard

Acknowledgement of Training

Date of Attendance: 11/15/24

Training : Safety Data Sheet

I confirm that I attended the training listed above. I listened, read, and understood the training, and I understand that as an employee, it is my responsibility to abide by **Hartley Medical's** *policy and procedures, in accordance with the training and laws set forth.*

I confirm that the following document(s) were given to me; SOP Employee Training for Compounded Nonsterile Preparation – Safety Data Sheet Attachment I SDS Training Material

If I have questions about the training, materials presented or **Hartley Medical's** *policy and procedures, I understand it is my responsibility to seek clarification from the Human Resources Department.*

Employee Name (Print) Amy Trinh

Employee Signature [signature] **Date** 11/15/24

hartleymedical
Serving the Standard

Acknowledgement of Training

Date of Attendance: 11/15/24

Training : Component Spill and Disposal

I confirm that I attended the training listed above. I listened, read, and understood the training, and I understand that as an employee, it is my responsibility to abide by **Hartley Medical's** *policy and procedures, in accordance with the training and laws set forth.*

I confirm that the following document(s) were given to me; SOP Employee Training for Compounded Nonsterile Preparations - Component Spill and Disposal

If I have questions about the training, materials presented or **Hartley Medical's** *policy and procedures, I understand it is my responsibility to seek clarification from the Human Resources Department.*

Employee Name (Print) Amy Trinh

Employee Signature [signature] **Date** 11/15/24

hartleymedical
Setting the Standard™

Acknowledgement of Training

Date of Attendance: 11/15/2024

Training : Understanding and Interpreting Certificates of Analysis (COA)

I confirm that I attended the training listed above. I listened, read, and understood the training, and I understand that as an employee, it is my responsibility to abide by **Hartley Medical's** *policy and procedures, in accordance with the training and laws set forth.*

I confirm that the following document(s) were given to me; SOP Employee Training for Compounded Preparation – Certificate of Analysis

If I have questions about the training, materials presented or **Hartley Medical's** *policy and procedures, I understand it is my responsibility to seek clarification from the Human Resources Department.*

Employee Name (Print) Amy Trinh

Employee Signature [signature] **Date** 11/15/2024

Understanding and Interpreting Certificates of Analysis (COA) Assessment

	Pass	Fail
Verify the document's authenticity	✓	
Check that the COA corresponds to the correct lot or batch	✓	
Identify key components	✓	
Confirm that assay and purity values fall within acceptable ranges	✓	
Understands when to approve or reject COA	✓	
Understands maintaining record and documentation of COA review	✓	

Quiz

1. What is the purpose of a COA? - Verify a substance meet required standard for using in compounding
   - ensure compliance with USP 797 + 795
2. List three critical pieces of information found on a COA.
   Manufacture / supplier information, specification, storage condition
3. A substance can be approved if the COA is missing lot or batch number? T/(F)

4. A substance can be approved if the assay/purity is outside the acceptable range? T/(F)

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	623495		**Inspection Information**
Legal Business Name:	Hartley Medical Center Pharmacy, Inc.	**Conference Call Date:**	1/17/2025
Doing Business As (DBA):	Hartley Medical Center Pharmacy, Inc.	**Start Time: 24-hour format (13:00)**	9:45
Address:	113 W Victoria St.	**End Time: 24-hour format (13:00)**	10:25
City:	Long Beach	**Onsite Inspection Date(s):**	1/21/2025; 1/22/2025
State:	California	**Start Time(s): 24-hour format (13:00)**	9:15; 9:05
Zip Code:	90805	**End Time(s): 24-hour format (13:00)**	16:20; 16:15
Telephone number:	562/595-7548	**Inspector Name(s):**	Paul N. Limberis, RPh
Toll free number:	888/671-2888	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	800/648-8550	**Observer Name/Affiliation (if applicable):**	Manisha Patel PharmD - CA BOP Inspector - Day 2.
Website:	www.hartleymedical.com	**Observer Name/Affiliation (if applicable):**	NA

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy- 47.07 and 93.00

Nonsterile - 3.0 - 3.2, 29.0 and 29.2

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	9:00	17:30	
Tuesday	9:00	17:30	
Wednesday	9:00	17:30	
Thursday	9:00	17:30	
Friday	9:00	17:30	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	William Allen Stuart	wstuart@hartleymedical.com	271118
Nonsterile Designated person(s)	Mirian Paik	mirian@hartleymedical.com	844133
Sterile Designated person(s)	Mirian Paik	mirian@hartleymedical.com	844133
Hazardous Designated person(s)	NA	NA	NA

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	William Stuart	PIC	Y
2	Mirian Paik	Pharmacist - Designated Person	Y
3	Amy Trinh	Pharmacist	Y
4	Vy Ninh	Pharmacist	Y
5	Cesar Benavidez	Technician	Y
6	Katelin Borja	Technician	Y
7	Sherie Marc	Technician	Y
8	Lisa Albarran	Pharmacy Account Representative	NA
9	Irene Domingo	Production Manager - Pain Management	NA
10	Gloria Chung	Pharmacy Support	NA

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.
In addition to the staff listed above there were an additional - 1 - Financial Services, 1- Regulatory Affairs, 1 - Cleanroom Support, 1 - QA Specialist, 1- Business Development and Sales, and 1- Pharmacy Account Representative.

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Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
California State Board of Pharmacy	Hartley Med Ctr Phcy Inc	Pharmacy	PHY 20643 & 5/1/2025
California State Board of Pharmacy	Hartley Medical Center Pharmacy Inc	Sterile Compounding	LSC 99011 & 5/1/2025
Drug Enforcement Administration	Hartley Medical Center Pharmacy	Controlled Substance - Pharmacy	AH8572984 & 10/31/2026

Inspector Notes: List states in which Non-Resident licenses are held: AK, AZ, AR, CO, CT, FL, DC, E, GA, HI, ID, IL, IN, IA, KS, KY, LA, MD, ME, MI, MN, MO, MS, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. MA - License not currently required. Hartley Medical Center Pharmacy is a compounding pharmacy specializing in sterile compounding of Intrathecal Medications only. These are all patient specific and delivered to the provider for administration to the patient via implantable IT pumps. The pharmacy also compounds one nonsterile product - Diltiazem Cream. These nonsterile prescriptions are received from the Long Beach VA. The compounded prescriptions are then sent back to the VA for dispensing to the patient. The pharmacy provides limited distribution of commercial products only to provider offices. The pharmacy does not participate in any trading platforms for short dated and overstock items. The pharmacy does not compound or dispense biologic products. The pharmacy does not compound or dispense any GLP1 products.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_NS20.2	Copy of API COAs and documentation of check

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	X	Central Fill/Processing/Shared Services	
Open to the Public		Nuclear Pharmacy	
Closed Door	X	Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	X
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)	X	Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	X
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	X
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	X
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	X
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous		Category 2 CSPs	X
Specific types:		Category 3 CSPs	X
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:	X	Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	X
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	6831	Total Pharmacists:	4
Nonsterile Compounding Room size:	46	Number of Compounding Pharmacists:	3
Nonsterile Compounding powder hoods number:	1	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	NA	Total Technicians:	3
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Number of Compounding Technicians:	3
Sterile Compounding Ante Room size:	135	Of technicians, how many are nationally certified?	0
Sterile Compounding Clean/Buffer Room size:	476	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	5	Total Other Unlicensed Personnel:	14
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	3 Tech : 4 Pharmacists
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	NA
Negative Pressure Sterile HD Room size:	NA		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	NA
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	Inspector was able to observe compounding directly through window into the clean room.

Volume Dispensed		**Volume Distributed**	
Total Prescriptions Dispensed/day:	110	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	90%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	<1%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	99%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)	0	0	December 2024
Arizona (AZ)	113	1	December 2024
Arkansas (AR)	0	0	December 2024
California (CA)	1802	0	December 2024
Colorado (CO)	9	0	December 2024
Connecticut (CT)	0	0	December 2024
Delaware (DE)	0	0	December 2024
District of Columbia (DC)	0	0	December 2024
Florida (FL)	1	0	December 2024
Georgia (GA)	0	0	December 2024
Hawaii (HI)	15	0	December 2024
Idaho (ID)	0	0	December 2024
Illinois (IL)	0	0	December 2024
Indiana (IN)	0	0	December 2024
Iowa (IA)	4	1	December 2024
Kansas (KS)	4	0	December 2024
Kentucky (KY)	17	0	December 2024
Louisiana (LA)	0	0	December 2024
Maine (ME)	0	0	December 2024
Maryland (MD)	1	0	December 2024
Massachusetts (MA)	0	0	December 2024
Michigan (MI)	0	0	December 2024
Minnesota (MN)	0	0	December 2024
Mississippi (MS)	0	0	December 2024
Missouri (MO)	0	0	December 2024
Montana (MT)	0	0	December 2024

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	95	1	December 2024
Nevada (NV)	15	0	December 2024
New Hampshire (NH)	0	0	December 2024
New Jersey (NJ)	53	0	December 2024
New Mexico (NM)	0	0	December 2024
New York (NY)	119	0	December 2024
North Carolina (NC)	0	0	December 2024
North Dakota (ND)	0	0	December 2024
Ohio (OH)	0	0	December 2024
Oklahoma (OK)	0	1	December 2024
Oregon (OR)	3	0	December 2024
Pennsylvania (PA)	42	0	December 2024
Rhode Island (RI)	0	0	December 2024
South Carolina (SC)	0	0	December 2024
South Dakota (SD)	0	0	December 2024
Tennessee (TN)	0	0	December 2024
Texas (TX)	11	0	December 2024
Utah (UT)	0	0	December 2024
Vermont (VT)	0	0	December 2024
Virginia (VA)	0	0	December 2024
Washington (WA)	93	0	December 2024
West Virginia (WV)	0	0	December 2024
Wisconsin (WI)	0	0	December 2024
Wyoming (WY)	0	0	December 2024
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	While the PIC was present on the days of the inspection, the Designated Person, Mirian Paik, predominantly participated in the inspection.
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours per week
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Mirian Paik, RPh - Designated Person, Meg Hogan - Regulatory Affairs, Irene Domingo - Production Manager, Katelin Borja - Pharmacy Technician
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	100%, 75% in CA and 25% out of state

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e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Notes
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	Yes	Less than 1% both in CA and out of state. The pharmacy provides limited distribution of commercial products only to provider offices.
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	No	While this is a closed door pharmacy, the licenses are all posted on a wall in the pharmacy.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The most recent SBOP Inspection was conducted on 3/22/2024. The Board inspects annually.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	1. The pharmacy did not have in place a policy and procedure regarding language interpretive services. 2. Staff pharmacy technicians did not wear identification as a pharmacy technician. 3. Pharmacy did not have a policy and procedure regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. 4. Review of updated policies for current USP <795> and <797>. Policies were updated and provided to the SBOP.

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e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Notes
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	Yes	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	PMP reporting waivers for zero dispensing. ME - allows pharmacy to report quarterly.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	Yes	DEA inspected in December 2022 with a close-out in January 2023. No deficiencies were noted.
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	Yes	The FDA inspected the pharmacy June 29, 2015 to July 8, 2015. A warning letter was issued on 4/21/2016 regarding six areas of non compliance with the FDCA. The pharmacy responded with the corrective actions taken. The pharmacy received the close-out letter on 9/26/2017.
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	NABP Compounding Accreditation 9/13/2022 to 9/12/2025

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National Association of Boards of Pharmacy®
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General Pharmacy Inspection

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Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Notes
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	Yes	PCAB accreditation in 2010, not renewed.
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are maintained on site for three years, minimally.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	Electronic records are maintained indefinitely. Paper records are maintained on site for 3 years.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic records are maintained indefinitely.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic records are maintained indefinitely. Paper records are maintained on site for 3 years.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Proprietary compounding and dispensing system (Microsoft Access programs) prevents records from being deleted.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Regulatory Affairs - Compliance Officer monitors all state and federal updates and informs the PIC and DP of updates that will require P&P updates.

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		Observation	Notes
	Personnel If any part of a question is no, enter "No" and explain the observation.		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Compliance Officer performs PSV checks at hire and every six months for licensed staff.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Compliance Officer performs PSV checks at hire and every six months for licensed staff. She also checks all in-state, out-of-state, and Federal licenses for renewals.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	No additional services provided requiring certification.
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	1 RPh: 1Tech, then with each additional pharmacist, two technicians are allowed. The pharmacy normally operates with 3 Tech : 4 RPh. Maximum number of staff working per day is 21.
	Facility and Security If any part of a question is no, enter "No" and explain the observation.		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Alarm Relay system is in place, includes door alarms, motion sensors and security cameras. Badge or key access is required. Alarm notifications are sent to the Owner/PIC and DP.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	API CII's are locked in cabinet in ante room and buffer room.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	A pharmacist will remain on site until the facility can be properly secured.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	

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		Observation	Notes
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	Yes	For product destroyed on-site, the pharmacy uses RX Destroyer and documents the product destruction on the DEA -41 form. Also some product is sent out to Triumvirate Environmental Services - reverse distributor.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Triumvirate Environmental Services.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	The pharmacy uses Precision Biowaste to remove any hazardous waste (Acetone, Acetonitrile and Trifluoracetic Acid) - used for HPLC instruments. The company is called as needed.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	Patients do not come to the pharmacy to pick up medications.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	Buffer room = 19.4 C, Ante Room = 20.8 C, NS Compounding Lab = 20.6 C.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Continuous electronic monitoring system - Setra. The temperature is recorded every 15 minutes by the system. Records are maintained electronically indefinitely. Temperature probes are calibrated or changed out annually.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	Product is pulled and quarantined. The product is then evaluated to assess for integrity, and if compromised, it is then removed from inventory.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Continuous electronic monitoring system - Setra. The temperature is recorded every 15 minutes by the system. Records are maintained electronically indefinitely. Temperature probes are calibrated or changed out annually. The range is set for 2-8 degrees C.

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		Observation	Notes
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Lab - 4.1 C,
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No frozen drug product is stored, ice packs only.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	If refrigerated, the product is moved to a working unit. The pharmacy also has a back-up generator on site.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	HVAC service on contract with routine maintenance.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	Product is pulled and quarantined. The product is then evaluated to assess for integrity, and if compromised, it is then removed from inventory.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	Two repeater pumps in the buffer room.
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The Compliance Officer ensures that all sources are FDA registered and appropriately licensed.

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		Observation	Notes
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	Yes	Piramal - Mitigo (Preservative-free Morphine)
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	AmeriSource Bergen - SmartSource, McKesson. For API sources - Medisca and Spectrum.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	Compliance Officer - vetting process for selecting vendors.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	LSPedia - DSCSA solutions to track supply chain distribution, as well as manual checks performed by pharmacists.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	LSPedia checks
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date

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		Observation	Notes
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	Electronically provided to the pharmacy and maintained electronically.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	Pharmacists - Mirian Paik and Amy Trinh have POA to sign the DEA 222 forms.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	Yes	Pharmacists - Mirian Paik and Amy Trinh have POA to place CSOS orders.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	APIs are tracked and reconciled quarterly. Finished dosage forms are electronically tracked perpetually.

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		Observation	Notes
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Notifications would be made to the BOP, DEA, and law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	Quarterly reconciliation is done by a staff pharmacist.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	10/25/2024. The complete inventories are done quarterly.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Monthly checks of all products
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Product is pulled at 3 months prior to expiration date.

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		Observation	Notes
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	N/A	All prescriptions are sent to provider offices.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Account representatives enter patient data upon receipt. Patient data is updated with provider contact and new orders.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	Approximately 80% are received electronically. Providers are well known to the pharmacy. Primarily interventional pain and anesthesiologists are the providers.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Reports would be made to the appropriate Board, DEA, law enforcement.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Providers are contacted for additional patient information, addresses are compared. Orders are scheduled dependent upon the patient appointment date with the provider.

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		Observation	Notes
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both controlled and non-controlled substances
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Pharmacists perform this at PV1 check prior to compounding.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	PVI is performed after data entry, before compounding. The pharmacy requests additional information from the providers and the VA to include patient allergies, other medications and conditions. If needed provider notes are also requested.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	Evaluation of dose changes, checking for titration needs.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	PACC guidelines
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Daily per each state requirement.

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		Observation	Notes
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Pharmacists will document these in the patient notes section of the patient profile.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	No	No integrated DUR database
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	Documentation of these DURs is done in the patient notes section of the patient profile.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	PV2 check performed by a pharmacist
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Labeled per strictest state requirement
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Orders are received in the Prime RX system for electronic orders only. Prescriptions are dispensed using the Access (proprietary) system.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Shredding service comes twice annually.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Notes
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	Seasonal packouts are used. The pharmacy performs testing routinely twice annually with data loggers.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Observation	Notes
	Patient Counseling and Communication If any part of a question is no, enter "No" and explain the observation.		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	Patients do not come to the pharmacy to pick up medications.
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	All injectable IT prescriptions are sent to provider offices for administration to the patient. Topical NS compounded diltiazem is sent to the VA in Long Beach to be dispensed to the patient. Prescription information is printed and provided with these. Providers perform the drug information for the IT medications. The pharmacy provides a phone number for patients to call if they have further questions.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	All prescriptions are sent to provider offices for administration to the patient. Providers perform the drug information. The pharmacy provides a phone number for patients to call if they have further questions.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	N/A	
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	

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		Observation	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Patient counseling is documented in the patient notes section of the patient profile.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	The DP, Mirian Paik oversees the CQI program for the pharmacy.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	P&Ps are electronically available.

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		Observation	Notes
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronic forms are used.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	

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		Observation	Notes
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Events are evaluated with occurrence. These are summarized quarterly at quality meetings.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Meetings are conducted quarterly.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	Changed processes to scan prescriptions and compounding records together, to ensure proper placement.
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Reports would be made to the appropriate Board of Pharmacy.

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		Observation	Notes
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	Self-Audits are performed by department on a continual basis.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Nonsterile Compounding Inspection for USP <795>

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		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		Environmental Control of the Non-Sterile Preparation Area, 21.1 (234-238)	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		Employee Training For Non-Sterile Products, 21.3, Staff Proficiency Testing Non-Sterile, 21.4 (241-247)	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		Gowning and Garbing in the Non-Sterile Preparation Area, 21.2 (239-240)	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		Selecting and procuring Components and Supplies 9.1, Component Receipt and Evaluation, 9.2. (102-103, 104)	6.2, 11

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		Observation	Inspector Notes	USP Reference(s)
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		Drug Storage, 9.3 (105-107)	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		Equipment, Equipment Calibration and Maintenance, 9.4 (108-110)	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		Chemical Spills, 22.1 (252-253)	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		Master Formulation and Compounding Record, 11.1 (133-134)	7.1, 11

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		Observation	Inspector Notes	USP Reference(s)
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		Labeling of Compounded Preparations, 13.1 (162-163)	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		Continuous Quality Improvement Program, 18.1 (181-185)	11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		Continuous Quality Improvement Program, Quality Related Events Report 18.1 Attachment III (186-190)	1.1.3, 11, 12.1, 12.2, 12.3

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		Observation	Inspector Notes	USP Reference(s)
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		CSP Handling, Storage, Packing and Transport. 20 (206-214)	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		CSP Handling, Storage, Packing and Transport. 20 (206-214)	11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		Drug /Product/Device Recall 18.4 (201-202)	12.1

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		Observation	Inspector Notes	USP Reference(s)
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes	Mirian Paik is the Designated Person for <795>.	1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11

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		Observation	Inspector Notes	USP Reference(s)
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	No		2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes		2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		

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		Observation	Inspector Notes	USP Reference(s)
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes	Gowns are not reused.	3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes	All garb is disposable	3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	Setra System continuous electronic monitoring system is in place. The temperature and humidity are also logged daily as well as on days when compounding occurs.	4.2

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		Observation	Inspector Notes	USP Reference(s)
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes	Probes are calibrated annually.	4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		21.2 C and Humidity 36%	4.2

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		Observation	Inspector Notes	USP Reference(s)
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	No		4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		70% IPA	5

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		Observation	Inspector Notes	USP Reference(s)
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes	In addition shelves are cleaned on a monthly basis.	5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes	The pharmacy cleans the shelves monthly.	5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	The pharmacy uses a CVE for nonsterile compounding.	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes	Mettler Toledo inspects and certifies the balances annually. Last certified 10/2024.	6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes	TSS inspects and certifies the CVE every six months.	6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2

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		Observation	Inspector Notes	USP Reference(s)
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes	Doc01_NS20.2.	6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	N/A	The one NS formulation compounded does not include water.	6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		NA - currently	6.2.1

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		Observation	Inspector Notes	USP Reference(s)
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes	This is digitally documented.	6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes	This information is digitally documented.	6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	N/A	Diltiazem includes an expiration date.	6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	No		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes	Electronically and hard copy availability.	6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes	The pharmacy uses Precision Biowaste to remove any hazardous waste (Acetone, Acetonitrile and Trifluoracetic Acid) - used for HPLC instruments. The company is called as needed.	6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes	Diltiazem Hydrochloride 2% in Surgilube Topical Gel 200 g.	7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	No		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	No	The dosage form is not included on the CR.	7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

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		Observation	Inspector Notes	USP Reference(s)
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes .***	Yes	The pharmacist verifies all weights and measurements prior to the product being compounded. This is documented on the weight receipts which are attached to the compounding record.	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes	All NS prescriptions are currently for Diltiazem 2% Topical Rectal Gel. These are sent to the pharmacy from a Long Beach VA Provider. The pharmacy then compounds the prescription and sends this back to the Long Beach VA. The Long Beach VA Pharmacy then dispenses this or ships it to the patient.	9

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		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	N/A		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes		12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documents the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1

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		Observation	Inspector Notes	USP Reference(s)
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		

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		Observation	Inspector Notes	USP Reference(s)
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	No accommodations to date.	3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1

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		Observation	Inspector Notes	USP Reference(s)
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.		Diltiazem HCl 2% 200 gm Rectal Gel	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2

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		Observation	Inspector Notes	USP Reference(s)
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3

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		Observation	Inspector Notes	USP Reference(s)
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes		8, 8.1, 9

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		Observation	Inspector Notes	USP Reference(s)
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes	The pharmacy does not perform any anticipatory compounding. The only product available to check was the Diltiazem HCl 2% 200 gm Rectal Gel.	12

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		Observation	Inspector Notes	USP Reference(s)
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	**Pharmacist - DP**	**Pharmacist**	**Technician**	**Technician**	**Technician**	**Notes**
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	

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	Employee Title	Pharmacist - DP	Pharmacist	Technician	Technician	Technician	Notes
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Missing	Missing	N/A	N/A	N/A	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes	Yes	Yes	Yes	
1.12	The training record for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
2.4	The annual competency assessment for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
2.8	The annual competency assessment for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	

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	Employee Title	Pharmacist - DP	Pharmacist	Technician	Technician	Technician	Notes
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Yes	Yes	N/A	N/A	N/A	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Yes	Yes	Yes	Yes	Yes	
2.12	The annual competency assessment for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A.* *Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Yes	Yes	Yes	Yes	Yes	

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.

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Glossary & References	USP <795>
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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Glossary & References	USP <795>
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

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Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		**Please note NABP did not review each SOP for alignment on USP <797>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions."*** ***If no, go to compliance statements.***	Yes		1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5

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		Observation	Inspector Notes	USP Reference(s)
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12

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		Observation	Inspector Notes	USP Reference(s)
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		17
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		Introduction (5)	1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		Compounding Personnel Training and Evaluation - Sterile Compounding, 2.1, Compounding Personnel Competency Exam, 2.2, Aseptic Technique, 2.3, Process and Personnel Compounded Sterile Preparation Validation, 2.4, Aseptic Manipulation Competency Evaluation, 2.5, Aseptic Manipulation Competency Evaluation-Batch Compounded Sterile Preparation, 2.6.	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3

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		Observation	Inspector Notes	USP Reference(s)
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		Garbing for the Sterile Preparation Area, 3.1, Hand Hygiene and Part of Aseptic Technique, 3.2, Gloving as Part of Aseptic Technique, 3.3 (42-44)	3, 3.3
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		Facilities and Engineering Controls, 4, Environment Control of the Sterile Preparation Area, 4.1, Laminar Air Workbench Maintenance, 4.2 (50-54)	4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		Certification and Recertification, 5, Third Party Testing of Sterile Preparation Area. (56)	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		Environmental Monitoring: Non-Viable Air Particle Count, 5.2, Microbiological Air and Surface Monitoring, 6, Environmental Monitoring-Viable Air Monitoring, 6.1, Environmental Monitoring-Surface Microbial Testing, 6.2, Environmental Monitoring - Preservative Free Batches, 6.3 (57-85)	6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		Cleaning, 7, Cleaning of the Aseptic Preparation Area, 7.0 (87-97)	7, 7.2 Box 7, Box 8

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		Observation	Inspector Notes	USP Reference(s)
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		Equipment, Equipment Calibration and Maintenance (107-109)	9.1, 10, 20
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		Selecting and Procuring Components and Supplies, 9.1, Component Receipt and Evaluation, 9.2, Drug Storage, 9.3 (101-106)	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		Master Formulation and Compounding Record, 11, Compound Record, 11.1, Employee Training for Compounding Documents, 11.2 (130-142)	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		Release Testing, 12, (LAL) Turbimetiric Kinetic Method Endotoxin Testing, 12.1, HPLC Testing for Quantitative Analysis of Compounded Products, 12.2, Out of Specification (OoS) Report and Documentation, 18.3 (143-159, 199-206)	12, 18, 20
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.		Labeling, 13, Labeling of Compounded Preparations, 13.1. (160-162)	13

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		Observation	Inspector Notes	USP Reference(s)
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		Handling, Storage, Packing and Transport, 20, Packaging, Shipping and Tracking, 20.1 (212-222)	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		Record Keeping, 20.1 (224)	20
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		Sterilization and Depyrogenation, 10, Verification of the Depyrogenation Oven, 10.1, Filter Integrity Testing, 10.2, Dry Healt Sterilization and Depyrogenation of Supplies, 10.3, Dry Heat Sterilization, 10.4, Steam Sterilization of Supplies, 10.5 (115-129)	10
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.3

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		Observation	Inspector Notes	USP Reference(s)
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	21
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	N/A		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4

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		Observation	Inspector Notes	USP Reference(s)
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only compounds sterile preparations (eg, does not prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	N/A		1.4
6.1	The product is prepared as a single dose for an individual patient.	N/A		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	N/A		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	N/A		1.1.2

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		Observation	Inspector Notes	USP Reference(s)
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2
	Facility Design and Engineering Controls			**4**
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.***	N/A		4.2.1 Glossary
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2

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		Observation	Inspector Notes	USP Reference(s)
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops)*** .	Yes		4.3.2
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	Yes		4.2.1, 4.3.2
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes	Gowning Room is ISO Class 8	4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	Yes	Ante Room is ISO Class 7 leading into a positive pressure Buffer Room.	4.1.2, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes	Line of demarcation is marked in yellow in the gowning room.	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.***	Yes	Pass-through box and hood pressure monitoring box, mounted on wall.	4.2.1, 4.3.1
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2

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		Observation	Inspector Notes	USP Reference(s)
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes	PECs are located away from the walls.	4.2.3
13.5	**Category 2 and Category 3**: PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5

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		Observation	Inspector Notes	USP Reference(s)
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		4, 9.1, 19.1
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	Yes	Sink is located on the clean side of the line of demarcation in the gowning room.	4.4

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		Observation	Inspector Notes	USP Reference(s)
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, inspector should answer statement as N/A.***	N/A		4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	Training of personnel	4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	Interlocked	4.2.1
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes	One moveable cart is used in the ISO 7 anteroom and ISO 7 buffer room. The other cart is permanently in the buffer room.	4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes		4.5
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	Continuous electronic monitoring system is used - Setra. Records are maintained electronically indefinitely. Excursion notifications are sent to the PIC and DP. Temperatures are also recorded daily.	4.2, 9.3.4, 19.1
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes	Continuous electronic monitoring system is used - Setra. Records are maintained electronically indefinitely. Excursion notifications are sent to the PIC and DP. Humidity readings are also recorded daily.	4.2, 9.3.4, 19.1
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes		4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	Inspected and calibrated every 12 months	4.2, 9.3.4
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	Inspected and calibrated every 12 months	4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	Yes		4.2, 9.3.4, 19.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	Yes		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		19.9 C - Buffer Room, 21 C - Ante Room	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		41% - Buffer Room, 32% - Ante Room	4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes		4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes	0.08	4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes	0.03 and 0.04	4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	Yes	There is an alarm in place.	4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	Yes		4.2.1
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	Yes		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6

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		Observation	Inspector Notes	USP Reference(s)
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	N/A		4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	N/A		4.2.1
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	Yes		4.2.6

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		Observation	Inspector Notes	USP Reference(s)
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	Yes	CVE for weighing API powders is located in the buffer room and is certified every six months.	4.2.6
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes		5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes	TSS Report 11/15/2024	4.2, 5, 20
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes	11/15/2024 - TSS	4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes	ISO 8 - Gowning Room, ISO 7 - Ante Room and ISO 7 - Buffer Room	4.1.1, 4.1.2, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes		5, 20
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH)**. ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes	Gowning Room	4.2.4, 5 Table 6

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		Observation	Inspector Notes	USP Reference(s)
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes		4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1

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		Observation	Inspector Notes	USP Reference(s)
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, inspector should answer statement as N/A.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	Yes	Particle counts are monitored continuously during compounding.	5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes	Reviewed facility sampling site map for viable air and surface monitoring.	6, 6.1, 6.2
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.***	Yes		6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	No	All air samples are incubated on site. For any identification, the samples are sent to US Micro.	6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	No	All surface samples are incubated on site. For any identification, the samples are sent to US Micro.	6.3
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab. If no, describe observations.***	N/A	All incubation is performed on site.	6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3***	Yes	Airborne samples are conducted weekly.	6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes	Serviced and calibrated annually.	6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes	One media device method is used.	6.2.2 Box 5
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes	None to date	6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes	None to date	6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to compliance statements.***	Yes		6.3

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		Observation	Inspector Notes	USP Reference(s)
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes	Weekly, and at the end of each batch prior to cleaning.	6.3, 6.3.1, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes		3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	Yes	No accommodations to date	3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	Yes	The pharmacy stocks hoods that cover all face areas along with goggles.	3.3
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	Yes		3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	Yes	Laundered and sterilized garb is used. These include, head bonnets, coveralls, and booties.	3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	Yes	The laundering and sterilization is performed by an outside vendor.	3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes	The pharmacy performs both batch and syringe compounding processes for media fill testing.	2.3, 20

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		Observation	Inspector Notes	USP Reference(s)
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3

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		Observation	Inspector Notes	USP Reference(s)
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	Yes		Box 2
	Cleaning and Disinfection			7
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used within PEC).	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2

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		Observation	Inspector Notes	USP Reference(s)
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes	Vesphene (Phenolic) - daily, SporKlenz - weekly, Isopropyl Alcohol 70% - disinfectant.	7.1.1 Box 7 <1072>
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved. Per USP, Inspector should check to see if agent is effective against Clostridium difficile.***	Yes	Spor-Klenz - weekly use.	7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1

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Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. ***If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.***	Yes	Vesphene	7.1.1
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes	Weekly	7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes	Weekly	7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes	Weekly	7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes	Weekly	7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the **PEC** at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	Yes		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes	Weekly	7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes	Weekly	7.2 Table 10
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes	Weekly	7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes	Weekly	7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes	Weekly	4.4, 7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
	Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Yes		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	Yes		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Supplies			9
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1

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		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes	Autoclave and oven are inspected and calibrated annually.	9.1, 9.3.4
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes	Repeater pumps are calibrated prior to each use.	9.1

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53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes	The two incubators are inspected and calibrated annually. A third incubator is used for BI used in the autoclave.	6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20˚C-25˚C and 30˚C-35˚C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	Reviewed for all three incubators.	6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	Yes		3.1
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	No accommodations to date	3.1

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55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		3.2

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		Observation	Inspector Notes	USP Reference(s)
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes	Category 3 garbing	3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #97.***	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	N/A	Category 3 garbing	3.3

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		Observation	Inspector Notes	USP Reference(s)
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).*** ***If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	N/A	Category 3 garbing	3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.		Hydromorphone 24mg/ml, Bupivacaine 36 mg/ml - 40 ml syringe for IT use.	
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2

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		Observation	Inspector Notes	USP Reference(s)
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.***	Yes		15
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2

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		Observation	Inspector Notes	USP Reference(s)
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	Yes		14.5, 15.2, 16.1
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	N/A		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates).*** ***These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes	A pharmacist is always present in the buffer room during compounding. All measurements are verified by a pharmacist during the compounding process.	2 Table 2, Table 3
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1

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		Observation	Inspector Notes	USP Reference(s)
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
	Sterilization and Depyrogenation			**10**
63.0	Does the pharmacy compound preparations with any nonsterile starting components? ***If the pharmacy does not compound preparations with any nonsterile starting components, inspector should answer question as N/A.***	Yes		10
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.2 USP <1229.4>

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		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."	Yes		10.2
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2

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		Observation	Inspector Notes	USP Reference(s)
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	N/A		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes	Steam sterilization is used for equipment only. No CSPs are steam sterilized.	10.3 USP <1229.1>

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		Observation	Inspector Notes	USP Reference(s)
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	Yes		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	Yes		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3

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		Observation	Inspector Notes	USP Reference(s)
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	Yes	Used with each cycle.	10.3 USP <1229.5> USP <1229.9>
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	Yes		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	Yes		10.3, 20

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		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm. If the pharmacy does not use this method, inspector should answer question as N/A.***	Yes		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	Yes		10.1

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		Observation	Inspector Notes	USP Reference(s)
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	Yes	The effectiveness of the cycle is verified annually using ECVs.	10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	Yes		10.1 USP <1228.4>
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			**11**
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to the compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1

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		Observation	Inspector Notes	USP Reference(s)
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: if pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	Yes		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include…Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>
	Establishing BUDs			**14**
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3

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		Observation	Inspector Notes	USP Reference(s)
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C).*** ***If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 13
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, Table 13
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	Yes		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	Yes		14.3 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	Yes		14.4.1 Table 14
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	Yes	Sterility testing is performed by ARL.	14.4.3 Table 14 USP <1225>

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		Observation	Inspector Notes	USP Reference(s)
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	Yes		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	Yes	Endotoxin testing is performed on site.	12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	Yes	This is performed with the stability studies at ARL.	14.4.3 Table 14 USP <788>, <789>
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	Yes	This is performed with the stability studies at ARL.	14.4.3 Table 14 USP <1207>
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	Yes		14.5

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		Observation	Inspector Notes	USP Reference(s)
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	N/A		14.5
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.*** ***Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	Yes	Antimicrobial effectiveness testing was performed by ARL for each preparation. MDVs are used only internally for preparation of patient specific IT prescriptions.	14.5 USP <51>

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Hartley Medical Center Pharmacy, Inc. dba Hartley Medical Center Pharmacy, Inc.
e-Profile ID: 623495
Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	Yes		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	Yes		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			12
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes		12.2

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Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used***	Yes		12.2, 14.2.3 USP <71>
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3

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		Observation	Inspector Notes	USP Reference(s)
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	Yes	Rapid Sterility test Celsis per ARL.	12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented." Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes		12.2

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Inspection Date: 1/17/2025, 1/21/2025 & 1/22/2025

		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight. Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	Yes		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	Yes		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	Yes		12.3

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		Observation	Inspector Notes	USP Reference(s)
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	Yes		12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	Yes		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	Yes		12.2, 12.3
	CSP Packaging, Shipping and Transport			**19**
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2

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		Observation	Inspector Notes	USP Reference(s)
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3
	Quality Assurance and Quality Control			18
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18 USP <1163>
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1

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		Observation	Inspector Notes	USP Reference(s)
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18

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		Observation	Inspector Notes	USP Reference(s)
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20

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		Observation	Inspector Notes	USP Reference(s)
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to the compliance statements.***	N/A		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	N/A		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	N/A		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	N/A		18.1

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		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). **Use the records tab to document records reviewed.**			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2, 2.1, 17 Table 2, Table 3

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file.
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).
Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding Inspection (Texas Sampling), review a total of 10 personnel records.)
- *Note: long-term employees may not have initial training available, if this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.
Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions	Demonstrating Knowledge and Competency of Core Skills (Section 2.1)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1. Personnel who perform or oversee compounding *or support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2). 2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas: -Hand hygiene -Garbing -Cleaning and disinfection -Calculations, measuring, and mixing -Aseptic technique -Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components) -Use of equipment -Documentation of the compounding process (eg, master formulation and compounding records) -Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area -Proper use of PECs -Principles of movement of materials and personnel within the compounding area 3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3). 4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3). 5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Designated Person	Category 2&3 only	Yes	Yes	Yes	Yes	A total of six employees perform sterile compounding.
#2	Pharmacist	Supervising/Direct Oversight	Category 2&3 only	Yes	Yes	Yes	Yes	
#3	Pharmacist	Supervising/Direct Oversight	Category 2&3 only	Yes	Yes	Yes	Yes	

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#4	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	Yes	
#5	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	Yes	
#6	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	Yes	
#7								
#8								
#9								
#10								

Inspector Instructions

1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position.
2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency.
3. Select the appropriate response for each item reviewed.
-Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards.
-Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column.
-Select "Missing" if the document is not present in the file.
-Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column.
4. Use the notes column to document any pertinent information.

Hand Hygiene and Garbing Competency Evaluation (Section 2.2)

USP requirements:
1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands.
2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row.
3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth.
4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days.
5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands.
6. Documentation includes, at minimum:
-Name of the person evaluated
-Evaluation date and time
-Media and components used including manufacturer, expiration date, and lot number
-Starting temperature for each interval of incubation
-Dates of incubation
-Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT)
-Results of the evaluation and any corrective actions
-Name of the observer and personnel reading and documenting the results

Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes

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Employee Record #	Employee Title	Personnel Function	CSP Category Type	Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially at least every 3 months Supervising Personnel: Initially and at least every 12 months				
#1	Pharmacist	Designated Person	Category 2&3 only	Yes	Yes	Yes	N/A	
#2	Pharmacist	Supervising/Direct Oversight	Category 2&3 only	Yes	Yes	Yes	N/A	
#3	Pharmacist	Supervising/Direct Oversight	Category 2&3 only	Yes	Yes	Yes	N/A	
#4	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	N/A	
#5	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	N/A	
#6	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	N/A	
#7								
#8								
#9								
#10								

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Inspector Instructions	Aseptic Manipulation Competency (Section 2.3)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information. 5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).	USP requirements: 1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel. 2. The pharmacy conducts media-fill testing as described in Box 2. 3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band. 4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days. 5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands. 6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device. 7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency. 8. Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: Initially and at least every 6 months Category 3 compounders: Initially and at least every 3 months Supervising Personnel: Initially and at least every 12 months					
#1	Pharmacist	Designated Person	Category 2&3 only	Yes	Yes	Yes	Yes	N/A	
#2	Pharmacist	Supervising/Direct Oversight	Category 2&3 only	Yes	Yes	Yes	Yes	N/A	
#3	Pharmacist	Supervising/Direct Oversight	Category 2&3 only	Yes	Yes	Yes	Yes	N/A	
#4	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	Yes	N/A	
#5	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	Yes	N/A	
#6	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	Yes	N/A	
#7	Pharmacy Technician	Compounder	Category 2&3 only	Yes	Yes	Yes	Yes	N/A	

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GLOSSARY USP <797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance* . A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.

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GLOSSARY USP <797>
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient*.
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.

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GLOSSARY USP <797>
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class*).
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.
Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.

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GLOSSARY USP <797>
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions)*. This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study)*.
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance.*
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.

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GLOSSARY USP <797>
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.
ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.

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GLOSSARY USP <797>
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package.*
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.

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GLOSSARY USP <797>
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.

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GLOSSARY USP <797>
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Sterility assurance level (SAL): See the entry for *Probability of a nonsterile unit* (PNSU).
Sterility: The absence of viable microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.
Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-um pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FL4317221
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☒ Non-sterile Compounding
			☒ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Lake Travis Pharmacy Partners dba Lake Hills Pharmacy

Physical Address: 12005 Bee Caves Rd. Ste 1A

City: Austin State: TX Zip: 78738

Mailing Address (if different from physical address): Same.

City: _____ State: _____ Zip: _____

Telephone: 512 608 9355 Toll Free # (NAC 639.708, NRS 639.23286): 833-493-1044

Fax: 512 792 4843 Contact Email: compliance@lakehillsrx.com

Website: www.lakehillsrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Rachael Kuretich

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24854

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Rachael Kuretich	NV Pharmacist Registration #: 24854
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Jobby John

Business Name: Lake Travis Pharmacy Partners LLC dba Lake Hills Pharmacy

Business Address: 12005 Bee Caves Rd. Ste 1A

City: Austin State: TX Zip: 78738

Telephone: 512-608-9355 Email: jobby@lakehillsrx.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Lake Hills Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jobby John
Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/10/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jobby John

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/13/2025

Date

Board Use Only	Date Received: 11/19/25	Amount: $500 ck 1529

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Lake Travis Pharmacy Partners, LLC (file number 801783534), a Domestic Limited Liability Company (LLC), was filed in this office on May 14, 2013.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on October 13, 2025.

Jane Nelson
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Lake Travis Pharmacy Partners dba Lake Hills Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 12005 Bee Cave Rd. Ste 1A

City Austin State TX Zip 78738

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 512 608 9355 Website www.lakehillsrx.com

Licensing Company Email compliance@lakehillsrx.com

Section 2: Personal Information

First Rachael Middle _____ Last Kuretich

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Navarro High School			2005 - 2009	
Address		City	State	Zip
6350 TX-123		Seguin	TX	78155
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
University of Texas at Austin			2009 - 2013	
Address		City	State	Zip
2515 Speedway		Austin	TX	78712
Diploma/Degree obtained, if any				
BS Kinesiology				

School Name			From - To (MM/YY – MM/YY)	
University of the Incarnate Word Feik School of Pharmacy			2014 - 2018	
Address		City	State	Zip
703 E Hildebrand		San Antonio	TX	78212
Diploma/Degree obtained, if any				
Pharm D				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Lake Hills Pharmacy			Feb 2022 - present
Business Address	**City**	**State**	**Zip**
12005 Bee Caves Rd #1A	Austin	TX	78738
Phone	**Title**	**Number of Employed Hours**	
512 608 9355	Pharmacist	6080	
Description of Duties			
review/dispense prescriptions, compound medications, patient counseling, Lab manager, USP compliance			

Business Name			From - To (MM/YY – MM/YY)
Gruene Road Pharmacy			2018 - 2022
Business Address	**City**	**State**	**Zip**
910 Gruene Rd #3	New Braunfels,	TX	78130
Phone	**Title**	**Number of Employed Hours**	
830 387 4378	Pharmacist	8320	
Description of Duties			
review/dispense prescriptions, compound medications, patient counseling			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Rachael Kuretich, certify that as the designated representative for Lake Travis Pharmacy Partners dba Lake Hills Pharmacy

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RMK I am at least 21 years of age;
3. RMK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RMK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RMK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RMK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RMK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rachael Kuretich

Print Name (First, Last)

RMK

Original Signature (electronic, copies or stamps not accepted)

11/13/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rachael Kuretich

Print Name (First, Last)

RMK

Original Signature (electronic, copies or stamps not accepted)

11/13/25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Rachael Kuretich, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

RMK

Original Signature

11/13/25

Date

Subscribed and Sworn to before me this 13 day of November 2025.

Bristelle McCullough

Notary Public Signature

BRISTELLE MCCULLOUGH
Notary Public, State of Texas
Comm. Expires 05-15-2027
Notary ID 134359040

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Lake Travis Pharmacy Partners dba Lake Hills Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable)

Physical Address 12005 Bee Cave Rd. ste 1A

City Austin State TX Zip 78738

Mailing Address (if different from physical address) same

City State Zip

Telephone 512 608 9355 Website www.lakehillsrx.com

Licensing Company Email compliance@lakehillsrx.com

Section 2: Personal Information

First Jobby Middle Last John

Alias(es, nick [redacted]

Date of Birth [redacted] SSN or ITI [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Z [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
THE UNIVERSITY OF TEXAS, COLLEGE OF PHARMACY		08/2009 - 5/2013	
Address	**City**	**State**	**Zip**
2409 UNIVERSITY AVENUE	AUSTIN	TX	78712
Diploma/Degree obtained, if any			
PHARM. D			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF TEXAS		01/2007 - 5/2009	
Address	**City**	**State**	**Zip**
2515 SPEEDWAY	AUSTIN	TX	78712
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
ST. THOMAS CENTRAL SCHOOL			
Address	**City**	**State**	**Zip**
1+x 62 + CRQ, KURAVANKUNNAM	TRIVANDRUM	KERALA	695043
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2023 – PRESENT	[redacted]			
7/2017 – 10/2023				
1/2015 – 6/2017				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
NIMBUS HEALTHCARE CORPORATION		05/2021 – PRESENT	
Business Address	**City**	**State**	**Zip**
12117 FM 2244	AUSTIN	TX	78738
Phone	**Title**		
512-608-9355	CEO		
Description of Duties			
CEO / FOUNDER			

Business Name		From - To (MM/YY – MM/YY)	
LAKE HILLS PHARMACY		01/2014 – PRESENT	
Business Address	**City**	**State**	**Zip**
12345 BEE CAVE RD, STE I-A	AUSTIN	TX	78738
Phone	**Title**		
512-608-9355	PRESIDENT / PHARMACIST IN CHARGE		
Description of Duties			
PIC for Lake Hills Pharmacy.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jobby John

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/10/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, Jobby John, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/10/2025

Date

Subscribed and Sworn to before me this 10 day of November 2025

Bristelle McCullough

Notary Public Signature

BRISTELLE MCCULLOUGH
Notary Public, State of Texas
Comm. Expires 05-15-2027
Notary ID 134359040

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Lake Travis Pharmacy Partners dba Lake Hills Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable):

Physical Address: 12005 Bee Cave Rd. Ste 1A

City: Austin State: TX Zip: 78738

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 512 608 9355 Toll Free # (NAC 639.708, NRS 639.23286): 833 493-1044

Fax: 512 792 4843 Contact Email: compliance@lakehillsrx.com

Website: www.lakehillsrx.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Rachael Kuretich

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24854

Name of Designated Person(s) as defined by revised USP-797 guidelines: Rachael Kuretich

Email of Designated Person(s): rachael@lakehillsrx.com

Telephone of Designated Person(s): 512 608 9355

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☒ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☒ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☒ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☒ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? October 2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☒ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☒ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? every 4 weeks

10. Will you be performing sterile hazardous drug compounding? Yes ☒ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

12. What laboratory performs your sterility or endotoxin testing?

Name: Prompt Praxis Laboratory

Address: 150 N. Fairway Drive

City: Vernon Hills State: IL Zip: 60061

Telephone:

13. What is your procedure for visual inspection of compounded sterile products?

Sterile compounded products are visually inspected before product is filtered to be free from all particulates. Visually inspected after filtration in final fill container. Visually inspected before final dispersing.

14. How often do you perform glove fingertip and medial fill testing?

Every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Include aseptic technique, hand hygiene, garbing procedures, cleaning protocol, facilities & PEC's, weighing/measuring ingredients, sterilization process, use of equipment, glove fingertip, media fill

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Daily - floors, high touch areas - PreEmpt followed by IPA 70%.
Daily - PEC - sterile TBI-3300, followed by sterile IPA 70%.
weekly - inside PEC - periodox RTU (sterile), followed by sterile IPA 70%.
monthly - floors, walls, ceilings, high touch areas, storage bins - Periodox RTU, followed by IPA 70%.
monthly - Inside PEC - sterile Periodox RTU, followed by sterile IPA 70%.

17. Who performs the sterile compounding process at your facility?

Michael Dominguez, Gyu-hee Min

18. Who is responsible and accountable for the sterile compounding process at your facility?

Rachael Kuretich

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

insulated mailers, ice packs

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rachael Kuretich

Name of Person who Completed the Form

Pharmacist

Title

[signature]

Signature (copies or stamps not accepted)

11/13/25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *LAKE HILLS PHARMACY*

License Number: *28908*

Address: *12005 BEE CAVE ROAD-STE 1A, AUSTIN, TX 78738*

Phone: *(512) 608-9355*

Email:

Class of License: *AS*

License Expiration: *11/30/2025*

DEA #: [redacted]

DEA Expiration: *03/31/2026*

Inspection Information

Type: *Compliance*

Purpose: *Routine*

Date: *09/22/2025*

Arrival Time: *10:00 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Rachel Kuretich *Pharmacist* *62559*

Witness

Syndi Hill

TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

JJ I am the Pharmacist-in-Charge (PIC) of *LAKE HILLS PHARMACY*, pharmacy license number *28908*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *09/22/2025*.

JJ I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

JJ I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

NA If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

JJ I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: JJ **Date:** *09/22/2025*

Printed Name: *Jobby John* **License No.(if applicable):** *53404*

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *LAKE HILLS PHARMACY* **License Number:** *28908*

Class of License: *AS*

Inspection Information

Type: *Compliance* **Purpose:** *Routine*

Date: *09/22/2025* **Arrival Time:** *10:00 AM* **Departure Time:** *12:00 PM*

Action Taken: *Inspection*

General Comments:

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

Comment

Annual controlled substance inventory completed on: 6/11/2025

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Not Applicable*

76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
04. Balance inspection	*Satisfactory*

Comment

Number of balances: 5

05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*
48. Drugs (procurement, temperature, security, out-of-date, samples)	*Satisfactory*
90. TSBP complaint notification	*Satisfactory*

Controlled Substances

10. Prescriptions separated	*Satisfactory*
24. Theft/Loss	*Not Applicable*

Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance	*Satisfactory*
30. Controlled substance invoices dated/initialed by pharmacist	*Satisfactory*
35. Controlled substance invoices separated	*Satisfactory*
46. Drug distribution	*Satisfactory*
53. Possession of controlled substances	*Satisfactory*
Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?)	*Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?)	*Satisfactory*
45. Proper dispensing/labeling	*Satisfactory*
54. Proper prepackaging procedures	*Not Applicable*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*
61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)	*Satisfactory*
37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)	*Satisfactory*
56. Prescription transfers	*Satisfactory*
67. Written drug information provided	*Satisfactory*
80. Patient counseling	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*
86. Absence of pharmacist records	*Satisfactory*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
92. Automated dispensing policy & procedures/SOPs	*Satisfactory*

Non-Sterile Compounding

03. Orderly/Clean/Hand Hygiene	*Satisfactory*
04. Balance inspection (for non-sterile compounding)	*Satisfactory*

Comment

Number of balances: 5 on license

05. Equipment Inspection	*Satisfactory*
06. Non-sterile Library	*Satisfactory*
32. Non-sterile compound label (Is label complete?)	*Satisfactory*
38. Area/Environment for non-sterile compounding	*Satisfactory*
43. Records for non-sterile compounding	*Satisfactory*
60. Documentation of non-sterile required training	*Satisfactory*

70. Required policies & procedures/SOPs	*Satisfactory*
87. Quality Control/Assurance	*Satisfactory*

Compounded Dosage Forms

Allergen extracts	*No*
Parenteral solutions	*Yes*
Parenteral suspensions	*No*
Preservative-free parenterals	*No*
Ophthalmic preparations	*No*
Oral or nasal inhalation preparations (not topical spray)	*Yes*

Comment

Compounds nasal sprays

Bath or soaks for live organs/tissues	*No*
Irrigations for wounds or body cavities	*No*
Any other sterile preparations (implants, pellets, etc) [list]	*No*
Investigational drugs	*No*
Blood products or other biological materials (wound care, autologous, eye drops, etc)	*No*
Any compounds using federally controlled substances Schedule I-V (list and percentage)	*Yes*

Comment

10% testosterone; ketamine

Does the pharmacy use lyophilizer?	*No*

Environment (Sterile)

S109. Is the cleanroom clean and free of objects that shed particles?	*Satisfactory*
S110. Is the cleanroom used only for sterile preparations?	*Satisfactory*
S119. Does the cleanroom contain only appropriate supplies?	*Satisfactory*
S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions?	*Satisfactory*
S115. Does the ante-area contain a hands-free sink with hot and cold running water?	*Satisfactory*
S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions?	*Satisfactory*
S106. Is the buffer area free from sources of water (e.g., sink, floor drains)?	*Satisfactory*
S108. Is there hands-free access to the buffer area?	*Satisfactory*

S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices?	*Satisfactory*
S112. Does the floor covering enable regular disinfection?	*Satisfactory*
S118. Are supplies stored above the floor to permit adequate floor cleaning?	*Satisfactory*
S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc?	*Satisfactory*
S116. Are temperature and humidity monitored, documented and within the required range?	*Satisfactory*
S167. Is there a thermometer available for the cleanroom and refrigerator(s)?	*Satisfactory*

Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc?	*Satisfactory*
S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations?	*Satisfactory*
S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas?	*Satisfactory*
S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area?	*Not Applicable*
S105. Does the CAI or CACI provide unidirectional airflow?	*Not Applicable*
S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area?	*Not Applicable*
S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer?	*Not Applicable*
S124. Is the PEC certified by an independent contractor every 6 months and when relocated?	*Satisfactory*
S125. Are prefilters inspected periodically and replaced as needed?	*Satisfactory*
S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device?	*Satisfactory*

Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies?	*Satisfactory*
S177. Does the pharmacy have lint-free towels or wipes?	*Satisfactory*
S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)?	*Satisfactory*
S176. Does the pharmacy have handwashing agents with bactericidal action?	*Satisfactory*
S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies?	*Satisfactory*

S179. Does the pharmacy have hazardous spill kits, if applicable?	*Satisfactory*
S171. Does the pharmacy have appropriate containers for needles and syringes?	*Satisfactory*
S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub?	*Satisfactory*
S178. Does the pharmacy have appropriate filters and filtration equipment?	*Satisfactory*
S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily?	*Satisfactory*
S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?	*Satisfactory*

High Risk CSPs

S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas?	*Satisfactory*
S231. Is sterility testing performed if CSPs are prepared in groups > 25, or	*Satisfactory*
S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or	*Satisfactory*
S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized?	*Satisfactory*
S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding?	*Satisfactory*
S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better?	*Satisfactory*
S165. Are filter integrity tests being performed and documented (e.g., bubble point test)?	*Satisfactory*
S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better?	*Satisfactory*

Sterile Library

S154. Does the pharmacy have a reference on injectable drugs?	*Satisfactory*
S155. Does the pharmacy have a specialty reference?	*Satisfactory*
S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters?	*Satisfactory*

Hazardous CSPs

S242. Do personnel wear protective apparel at all times when hazardous drugs are handled?	*Not Applicable*
S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs?	*Not Applicable*

S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations?	*Not Applicable*
S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging?	*Not Applicable*
S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	*Not Applicable*
S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)?	*Not Applicable*
S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	*Not Applicable*
Does the pharmacy have a plan to comply with USP <800> by the implementation date?	*Not Applicable*
Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)?	*Not Applicable*
Is hazardous drug waste quarantined in a designated area?	*Not Applicable*
Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)?	*Not Applicable*

Personnel Cleansing, Garbing, Hand Hygiene

S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)?	*Satisfactory*
S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)?	*Satisfactory*
S194. Before entering the buffer area, do compounding personnel remove cosmetics?	*Satisfactory*
S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings?	*Satisfactory*
S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders?	*Satisfactory*
S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water?	*Satisfactory*
S192. Are personnel with an apparent illness or open lesions compounding sterile preparations?	*Satisfactory*
S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed?	*Satisfactory*
S201. Do compounding personnel engage in proper hand hygiene?	*Satisfactory*
S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer?	*Satisfactory*
S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves?	*Satisfactory*

S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched?	*Satisfactory*

Cleaning/Disinfection Procedures

S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)?	*Satisfactory*
S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	*Satisfactory*
S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)?	*Satisfactory*
S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies?	*Satisfactory*
S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly?	*Satisfactory*
S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)?	*Satisfactory*

Environmental Sampling

S270. Is surface sampling conducted in all ISO classified areas on a periodic basis?	*Satisfactory*
S272. Is viable air sampling performed?	*Satisfactory*
S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months?	*Satisfactory*
S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)?	*Satisfactory*

Records of CSPs

S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?	*Satisfactory*
S253. Do compounding records include the date and time of preparation of a CSP?	*Satisfactory*
S254. Do compounding records include the complete formula of a CSP?	*Satisfactory*
S257. Do compounding records include the quantities of materials used in a CSP?	*Satisfactory*
S255. Do compounding records include the signature or initials of who prepared a CSP?	*Satisfactory*
S256. Do compounding records include the signature or initials of who conducted the final check of a CSP?	*Satisfactory*
S258. Do compounding records include the container used and the number of units prepared for a CSP?	*Satisfactory*
S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP?	*Satisfactory*

S260. Do compounding records include the documentation of performance of quality control procedures?	*Satisfactory*
S261. Are master worksheets and preparation worksheets for batch compounding complete?	*Satisfactory*
S262. Are master worksheets developed and approved by a pharmacist?	*Satisfactory*

General Operational Requirements

S166. Is a pharmacist available at all times (24/7)?	*Satisfactory*
S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs?	*Satisfactory*
S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)?	*Satisfactory*
S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or,	*Not Applicable*
S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)?	*Not Applicable*
S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states?	*Satisfactory*

Comment

Licensed in WA, ID, MT, WY, CO, AZ, TX, OK, KS, ND, IA, MO, AR, LA, GA, MI, WI, IL, TN, FL, NY, NJ, ME

Office Use Compounding & Distribution of CSPs

S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use?	*Not Applicable*
S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution?	*Not Applicable*
Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)?	*No*

Quality Control & Verification of Compounding Accuracy

S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP?	*Satisfactory*
S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined?	*Satisfactory*
S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories?	*Satisfactory*
S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility?	*Satisfactory*

S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons?	*Not Applicable*

Veterinary Compounding

Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding?	*No*
Does the pharmacy meet the same standards for animal compounding as human compounding?	*No*
Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients?	*No*
Does the pharmacy document if the animal is a pet or used for food?	*No*
Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals?	*No*
Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals?	*No*
Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals?	*No*

Label

S209. Is the CSP properly labeled to include the generic name(s), and	*Satisfactory*
S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy?	*Satisfactory*
S211. Does the label include a beyond-use date?	*Satisfactory*
S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and	*Satisfactory*
S214. Quantity, and	*Satisfactory*
S215. Appropriate ancillary instructions, such as storage or cautionary statements, and	*Satisfactory*
S216. Any device-specific instructions, if appropriate?	*Satisfactory*
S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing?	*Satisfactory*

Training & Competency Testing

S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*
S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	*Satisfactory*

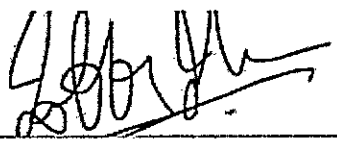
S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program? *Satisfactory*

S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)? *Satisfactory*

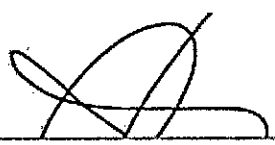
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Jobby John



Synthia Hill

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FL4317221	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY-COLLECTOR	02-16-2023

LAKE HILLS PHARMACY
12005 BEE CAVE RD STE 1A
BEE CAVE, TX 787386387

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
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Form DEA-223 (9/2016)

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 28908

LAKE HILLS PHARMACY

License Information

License Status Active
License # 28908
Expiration Date 11/30/2027
Date License Issued 11/26/2013

Address

12005 BEE CAVE ROAD-STE 1A
AUSTIN, TX 78738
County TRAVIS
Phone (512) 608-9355

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy
Community Sterile Compounding
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
JOHN, JOBBY

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	Yes

Translating services (Listed Below If Available)

Spanish

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and/or Inspection Reports

- 700405 28908 LAKEHILLSPHARMACY 2020-09 09-2025.pdf
- 700405 28908 LAKEHILLSPHARMACY 2023-01 01-2028.pdf
- 700405 28908 LAKEHILLSPHARMACY 2024-07 07-2029.pdf
- 700405 28908 LAKEHILLSPHARMACY 2025-09 09-2030.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	Yes

Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	Yes
Compounding Non-Sterile	Yes
24 Hour Service	Yes
Closed Door	No
Compounding, Office Use	No
Home Delivery	Yes
Infusion	Yes
Pharmacist Administered Immunizations	Yes
Veterinary Prescriptions	Yes
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment Information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
ALONSO, DANIEL EDUARDO	70785	07/28/2022	09/30/2026	Staff	Active
GUNTER, CHRISTINA MARIE	48660	07/09/2010	12/31/2026	Staff	Active
GURLEY, PATRICK CLEBURNE	69335	09/02/2021	05/31/2027	Staff	Active
JOHN, JOBBY	53404	07/18/2013	04/30/2027	PIC	Active
KURETICH, RACHAEL	62559	06/21/2018	05/31/2026	Staff	Active
MIN, GYU-HEE	74680	08/29/2024	06/30/2026	Staff	Active

Page 1 of 1 20 View 1 - 6 of 6

Texas Registered Technicians/Trainees Employment Information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
CHANG, SELINA	339024	05/03/2022	05/31/2026	Staff	Active
DAVILA, MICHELLE	242096	04/10/2015	03/31/2027	Staff	Active
DOMINGUEZ, MICHAEL	153745	02/07/2008	09/30/2027	Staff	Active
GALDAMEZ, JENNIFER ELIZABETH	315587	12/21/2020	01/31/2027	Staff	Active
LEFRESNE, MONICA KATHLEEN	313688	10/27/2020	06/30/2027	Staff	Active
LEMA, MELISSA MARIE	351650	02/21/2023	02/28/2027	Staff	Active
MAURICIO, MALCOLM	221998	08/13/2013	05/31/2026	Staff	Active
MCCULLOUGH, BRISTELLE J	113126	05/12/2004	11/30/2026	Staff	Active
RAMON, VINCENT MICHAEL	280560	02/27/2018	03/31/2026	Staff	Active
RUIZ, ROBERT REY	146861	11/18/2008	03/31/2027	Staff	Active
SONNIER, ALONNA MARIE	134591	06/16/2006	06/30/2026	Staff	Active
STOKES, WILLIAM LEE	183120	08/12/2010	01/31/2027	Staff	Active

Page 1 of 1 20 View 1 - 12 of 12

Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode
NIMBUS CLOUD SCRIPTS	28908-SAPH-7244	12117 BEECAVES RD STE 1	AUSTIN	TX	78738

Page 1 of 0 20 View 1 - 1 of 1

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
LAKE TRAVIS PHARMACY PARTNERS, LLC	OWNER	,			
JOHN, JOBBY	OFFICER	,			

Page 1 of 1 20 View 1 - 2 of 2

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☑ Retail/Community ☑ Dangerous drugs ☑ Controlled substances DEA #: FT5315622 ☑ Non-sterile Compounding ☑ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Logos Pharmacy

Physical Address: 7543 W Waters Ave

City: Tampa State: FL Zip: 33615-1511

Mailing Address (if different from physical address): Same As Above

City: _____ State: _____ Zip: _____

Telephone: 813-886-2800 Toll Free # (NAC 639.708, NRS 639.23286): 855-564-6779

Fax: 813-886-2822 Contact Email: info@logospharmacy.org

Website: www.logospharmacy.org

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Carlos Martinez Morejon

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24770

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Carlos Martinez Morejon	NV Pharmacist Registration #: 24770
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): N/A

Corporation/Organization Name: Tradeline SH, Inc

Mailing Address: 7543 W Waters Ave, Tampa, FL

City: Tampa State: FL Zip: 33615-1511

Telephone: 813-886-2800 Email: info@logospharmacy.org

Contact Person Name: Raafat Habib

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Logos Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Raafat Habib

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10-10-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rafaat Habib

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

10-10-2025

Date

Board Use Only	Date Received: 10/13/25	Amount: $510 ck 2484

LOGOS PHARMACY

September 19, 2025

Dear Board of Pharmacy,

I, Raafat Habib, am the sole officer of Tradeline SH, Inc dba Logos Pharmacy. My contact information is listed below.

Name	Title	Phone	Address
Raafat Habib	President	8138862800	Work: 7543 W Waters Ave Tampa, FL 33615 Home: [redacted]

Sincerely,



Raafat Habib

7543 W Waters Ave
Tampa, FL 33615
USA

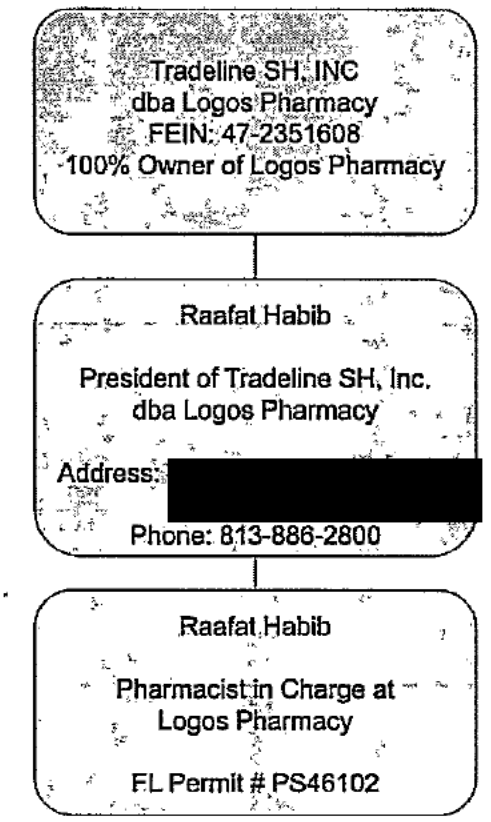
PHONE 813-886-2800
FAX 813-886-2822
EMAIL info@logospharmacy.org
WEBSITE www.logospharmacy.org

LOGOS PHARMACY

September 19, 2025

Dear Board of Pharmacy,

Please see the org chart and officer information for the sole officer of Tradeline SH, Inc dba Logos Pharmacy.



7543 W Waters Ave
Tampa, FL 33615
USA

PHONE 813-886-2800
FAX 813-886-2822
EMAIL info@logospharmacy.org
WEBSITE www.logospharmacy.org

State of Florida
Department of State

I certify from the records of this office that TRADELINE SH, INC. is a corporation organized under the laws of the State of Florida, filed on November 13, 2014, effective January 1, 2015.

The document number of this corporation is P14000092816.

I further certify that said corporation has paid all fees due this office through December 31, 2025, that its most recent annual report/uniform business report was filed on April 25, 2025, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-seventh day of May, 2025



Secretary of State

Tracking Number: 4175467954CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Logos Pharmacy

Pharmacy/Wholesaler License # (if applicable) N/A- Initial Application

Physical Address 7543 W Waters Ave

City Tampa State FL Zip 33615-1511

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 813-886-2800 Website www.logospharmacy.org

Licensing Company Email info@logospharmacy.org

Section 2: Personal Information

First Carlos Middle _____ Last Martinez Morejon

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Tampa State FL Zip 33614

Telephone [redacted] Email info@logospharmacy.org

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Lake Erie College of Osteopathic Medicine			08/18/-06/22	
Address		**City**	**State**	**Zip**
5000 Lakewood Ranch Blvd		Bradenton	FL	34211
Diploma/Degree obtained, if any				
PharmD				
School Name			**From - To (MM/YY – MM/YY)**	
Hillsborough Community College				
Address		**City**	**State**	**Zip**
4001 W Tampa Bay Blvd		Tampa	FL	33644
Diploma/Degree obtained, if any				
A.A. Science				
School Name			**From - To (MM/YY – MM/YY)**	
Concord Institute				
Address		**City**	**State**	**Zip**
4202 W Spruce St		Tampa	FL	33607
Diploma/Degree obtained, if any				
Pharmacy Technician Diploma				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/17- Current	[redacted]	Tampa	FL	33614
08/12-06/17		Tampa	FL	33607

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Logos Pharmacy			07/24 - Current	
Business Address	**City**		**State**	**Zip**
7543 W Waters Ave	Tampa		FL	33615
Phone	**Title**		**Number of Employed Hours**	
813-886-2800	Pharmacist		2340	
Description of Duties				
Type Rxs, Verify Rxs, Dispense RXs, Manage Recordkeeping, Transfer RXs, Order inventory				

Business Name			From - To (MM/YY – MM/YY)	
Anazao Health			08/22-7/24	
Business Address	**City**		**State**	**Zip**
5710 Hoover Blvd	Tampa		FL	33634-5339
Phone	**Title**		**Number of Employed Hours**	
813-882-4500	Pharmacist		5000+	
Description of Duties				
Type Rxs, Verify Rxs, Dispense RXs, Manage Recordkeeping, Transfer RXs				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Carlos Martinez Alvarejos, **certify that as the designated representative for** Logos Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Carlos Martinez Alvarejos
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9.23.25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carlos Martinez Florejon

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9.23.25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Hillsborough

I, Carlos Martinez Florejon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9.25.25

Date

Subscribed and Sworn to before me this 25 day of Sept 2025

Notary Public Signature

TAYLOR HENDERSON
Notary Public
State of Florida
Comm# HH284394
Expires 7/5/2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Logos Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) Nevada N/A - New Applicant; FL PH290

Physical Address 7543 W Waters Ave

City Tampa State FL Zip 33615

Mailing Address (if different from physical address)

City State Zip

Telephone 813-886-2800 Website www.logospharmacy.org

Licensing Company Email info@logospharmacy.org

Section 2: Personal Information

First Raafat Middle Mossad Last Habib

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Trinity State FL Zip 34655

Telephone [redacted] Email info@logospharmacy.org

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Assiut University - Faculty of Pharmacy			
Address	**City**	**State**	**Zip**
55PC+X4V شارع المكتبات ،	El Fateh, Assiut Governorate	Egypt	71515
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Coptic High School (School closed)		08/88-06/91	
Address	**City**	**State**	**Zip**
Street address unknown	Minya Governorate	Egypt	2364880
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Coptic Middle School (School Closed)		08/84-06/88	
Address	**City**	**State**	**Zip**
Street address unknown	Minya Governorate	Egypt	2364880
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/22- Current	[redacted]	Trinity	FL	34655
03/14-03/22		Trinity	FL	34655
From - To (MM/YY - MM/YY) Ad				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Logos Pharmacy			From - To (MM/YY – MM/YY): 01/15- Current
Business Address: 7543 W Waters Ave	City: Tampa	State: FL	Zip: 33765
Phone: 813-886-2800	Title: Manager and Owner		
Description of Duties: Manage and Supervise the pharmacy team			

Business Name: Inspire Pharmacy			From - To (MM/YY – MM/YY): 04/18-03/22
Business Address: 2019 Gulf to Bay Blvd	City: Clearwater	State: FL	Zip: 33765
Phone: 727-441-6900	Title: Partner		
Description of Duties: 50% partner - No pharmacy duties			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10-7-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Raafat Habib

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-7-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Hillsborough

I, Raafat Habib, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-7-2025

Date

Subscribed and Sworn to before me this 7TH day of October 2025

Luis Taborda

Notary Public Signature

LUIS TABORDA
Notary Public
State of Florida
Comm# HH697724
Expires 7/13/2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Logos Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 7543 w Waters Ave

City: Tampa State: FL Zip: 33615

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 813-886-2800 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 813-886-2822 Contact Email: info@logospharmacy.org

Website: www.logospharmacy.org

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Raafat Habib

Supervising/Managing Pharmacist NV Pharmacist Registration #: _____

Name of Designated Person(s) as defined by revised USP-797 guidelines: Carlos Martinez Morejon

Email of Designated Person(s): cmartinez@logospharmacy.org

Telephone of Designated Person(s): 813-886-2800

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 07/21/2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 month

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? monthly

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Semaglutide/ Glycine 5mg/20mg/ml (2ml) solution

Tirzepatide/ Glycine 18mg/20mg/ml (2ml) solution

NAD+ 100mg/ml (10ml) solution

Glutathione 200mg/ml (10ml) solution

Testosterone Cypionate in grapeseed oil 200mg/ml (5ml) solution

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetrics Lab

Address: 11880 28th St #210

City: St. Petersburg State: FL Zip: 33716

Telephone: (727) 209-5778

13. What is your procedure for visual inspection of compounded sterile products?
a. Use higher illumination intensity sufficient to detect particles for preparations where solutions are colored, opaque or in containers other than clear glass. 4. Assess preparations for particulate, including the following:
1. Precipitate.
2. Non-dissolved particles.
3. Non-viable particulate.
4. Viable particulate.
5. Small rubber cores.
6. Discoloration.

14. How often do you perform glove fingertip and medial fill testing?
Every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
1. Compounding personnel must be able to demonstrate proficiencies in at least the following areas prior to compound and every 6 month:
a. Standard operating procedures.
b. Hand hygiene.
c. Garbing (i.e., gloving, donning and doffing for non-hazardous drug handling and compounding).
f. Sanitization Procedures (i.e., cleaning and disinfecting).
g. Aseptic techniques, which includes its assessment by:
i. Gloved fingertip and thumb sampling.
ii. Media-fill testing.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
PEC(s) and equipment inside the PEC(s) Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected. Equipment and all interior surfaces of the PEC daily before compounding and when surface contamination is known or suspected. Monthly for entities compounding
Category 1 and/or Category 2 CSPs. Removable work tray of the PEC, when applicable Work surface of the tray daily on days when compounding occurs. All surfaces and the area underneath the work tray monthly. Work surface of the tray before compounding on days when compounding occurs. Work surface of the tray monthly. All surfaces and the area underneath the work tray monthly. Surfaces of sinks must be cleaned each day of use. Surfaces of the sinks must be disinfected each day of use. At least monthly. Pass-through chambers Daily on days when compounding occurs. Daily on days when compounding occurs.

17. Who performs the sterile compounding process at your facility?

Carlos Martinez Morejon & Melissa Fulladolsa

18. Who is responsible and accountable for the sterile compounding process at your facility?
Carlos Martinez Morejon & Raafat Habib

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Package are shipped through UPS or FedEx on boxes dedicated to preventing leakage and breakage from ULINE overnight for refrigerated items with 2 (6oz) ice pack inside package.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? 2 - BSC Type A		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Patients are provided with written instructions on safe handling (gloves, handwashing, no crushing), proper storage, and disposal (no trash or flushing, return via take-back programs or HD containers). Containers and vials are also labeled with hazard warnings and disposal instructions

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
Sterile Technician are to successfully pass the Critical Point: Sterile Compounding & Hazardous Drugs eLearning 34.5 credit hours. In addition to succesufully passing course, technicains would get training and show understanding for sterile compounding by demonstrating proficiencies in at least the following areas prior to compound and every 6 months:
a. Standard operating procedures.
b. Hand hygiene.
c. Garbing (i.e., gloving, donning and doffing for non-hazardous drug handling and compounding).
f. Sanitization Procedures (i.e., cleaning and disinfecting).
g. Aseptic techniques, which includes its assessment by:
i. Gloved fingertip and thumb sampling.
ii. Media-fill testing.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?
every 6 months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes ■ No

4. What is the frequency for completing volumetric active air sampling?
every 6 months

5. What is the frequency for completing surface sampling? Monthly		
6. What is the frequency for using sporicidal agents? Monthly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carlos Martinez Morejon

Name of Person who Completed the Form

Pharmacist

Title

Signature (copies or stamps not accepted)

9.30.25

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

Logos Pharmacy
7543 W. Waters Ave
Tampa FL 33615
813-886-2800

⚠ Safe Handling & Disposal of Hazardous Medicines

1. Handling at Home

- Always wear disposable gloves when touching the medicine.
- Wash hands before and after handling.
- Keep away from children, pets, and pregnant caregivers.

2. Storage

- Keep medicine in the original container with label.
- Store in a cool, dry place, away from food.
- Do not mix with other medicines.

3. Disposal

- Do NOT throw in trash or flush down the toilet.
- Return unused/expired medicine to the pharmacy or an authorized take-back program.
- If given a special disposal container or bag, always use it.
- Place gloves, packaging, and cleanup materials in a sealed plastic bag before discarding.

4. Spills & Accidents

- Clean small spills with disposable paper towels.
- Wear gloves while cleaning.
- Wash skin immediately with soap and water if exposed.
- If medicine gets into your eyes, rinse well and seek medical help.

5. Labels & Warnings

Look for these warnings on your container:

- ⚠ "Hazardous—Handle with Care"
- ⃠ "Do Not Crush or Open"
- "Wear Gloves When Handling"

Logos Pharmacy **7543 W. Waters Ave,** **Tampa, FL 33615**	SOP CODE:	USA – STRL – P1.1.2.0 REVISION NUMBER: 2 . 2 . 0
	ISSUE DATE:	August 29, 2024
	IMPLEMENTATION DATE:	August 30, 2024
	☒ CONTROLLED COPY	☐ UNCONTROLLED COPY ____

TITLE : PERSONNEL – MANAGING – PROFESSIONAL DEVELOPMENT – COMPOUNDING PRACTICES

DRAFTED BY:	**SIGNATORY:**	**Carlos Martinez**	SIGNATURE	08/29/2024 DATE
CM	**TITLE:**	**Pharmacist**		
VERIFIED BY:	**SIGNATORY:**	**Raafat Habib**	SIGNATURE	08/29/2024 DATE
RMH	**TITLE:**	**Pharmacy Manager**		
APPROVED BY:	**SIGNATORY:**	**Raafat Habib**	SIGNATURE	08/29/2024 DATE
	TITLE:	**DESIGNATED PERSON**		
APPROVED BY:	**SIGNATORY:**	**Carlos Martinez**	SIGNATURE	08/29/2024 DATE
CM	**TITLE:**	**DESIGNATED PERSON**		

RELATED LOGS & FORMS

RECORD	SPECIFICATION / DESCRIPTION
USA - STRL - L1.1.2.0	Training, Competency and Compliance Log
USA - STRL - F1.1.2.0	Personnel Roles and Responsibilities

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE
USA – STRL – P0.1.1.0	Preamble – Implementing – Standard Operating Procedures – Compounding Practices
USA – STRL – P0.2.1.0	Preamble – Customizing – Standard Operating Procedures – Compounding Practices
USA – STRL – P0.3.1.0	Preamble – Recording – Good Documenting Practices – Compounding Practices
USA – STRL – P1.1.2.1	Personnel - Managing - Professional Development - Compounding Practices (HD)
USA – STRL – P0.5.2.1	Personnel - Managing - Hazard Communication Program - Compounding Practices (HD)
USA – STRL – P1.3.2.1	Personnel - Managing - Medical Surveillance - Compounding Practices (HD)

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This SOP is for customer's internal use only. Any reproduction, reprint or copy, in electronic or print version, is strictly prohibited without the expressed written consent of Medisca. This SOP is intended to be used as a guideline and should not be relied on by end-user licensed pharmacist or other appropriately licensed professional "as is". Adjustments are required to be made by end-user licensed pharmacist or other appropriately licensed professional prior to use in order to be compliant with applicable laws, operating practices, and industry guidelines. Any changes to this SOP must be validated, approved and authorized for use by the end-user licensed pharmacist or other appropriately licensed professional prior to use. Medisca shall not be liable for, and does not warrant, the accuracy or completeness of the content of this SOP. In all cases, it is the responsibility of the licensed pharmacist or other appropriately licensed professional to ensure compliance with local, state, provincial, federal regulations, laws and industry practices prior to use.

4. Compounded Sterile Preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
5. Designated Person: One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.

FREQUENCY

1. Complete initial theoretical and practical competency requirements prior to starting sterile non-hazardous drug handling and compounding.
2. Perform on an ongoing basis once personnel have completed and passed initial training program.
3. Perform upon changes in requirements with respective regulatory boards and/or State or Federal regulations.
4. Complete a comprehensive written refresher-training program with competency assessment within a twelve-month period, and every twelve months.
5. Perform retraining in the recognition of identified deficiencies or demonstrated errors in performance.
6. Perform retraining in the event of structural, functional and/or operational change to the compounding facility.
7. **Complete initially and at least every 12 months in at least the following:**
   - Hand hygiene
   - Garbing
   - Cleaning and disinfection
   - Calculations, measuring, and mixing
   - Aseptic technique
   - Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
   - Use of equipment
   - Documentation of the compounding process (e.g., master formulation and compounding records)
   - Principles of movement of materials and personnel within the compounding area

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TITLE : PERSONNEL – MANAGING – PROFESSIONAL DEVELOPMENT – COMPOUNDING PRACTICES

8. Competency Testing in Aseptic Manipulation and Media Fill:

8.1- For personnel compounding Category 1 and Category 2 CSPs, the aseptic manipulation and media fill competency must occur initially and at least every 6 months thereafter. For personnel compounding Category 3 CSPs, the aseptic manipulation and media fill competency must occur initially and at least every 3 months thereafter

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SPECIAL CIRCUMSTANCE

1. If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency.

PROCEDURE

This SOP is divided into the following sections:

1. Applicability
2. Qualification
3. Training requirements
4. Competency Requirements
5. Compliance Requirements

1. Applicability

1. Documentation, directly or indirectly, related to a standard operating procedure, or any other documentation requirements, must comply with all laws and regulations of the applicable regulatory jurisdiction.

2. Qualification

a. Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions

3. Training Requirements

1. Compounding personnel must be able to demonstrate proficiency in at least the following areas:
   a. Standard operating procedures.
   b. Hand hygiene.
   c.
   d. Garbing (i.e., gloving, donning and doffing for non-hazardous drug handling and compounding).
   e. Handling, receiving, unpacking and storing procedures.
   f. Proper use of primary engineering controls (PECs), which includes, however, may not be limited to:

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i. Maintenance and monitoring.

ii. Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 environment.

iii. Principles related to pressure differentials between ISO class environments.

g. Sanitization Procedures (i.e., cleaning and disinfecting).

h. **Aseptic techniques, which includes its assessment by:**

i. Gloved fingertip and thumb sampling for Category 1 and 2 at least every 6 months and Category 3 at least every 3 months

ii. Media-fill testing with Post-GFT and Surface Sampling for Category 1 and 2 at least every 6 months and Category 3 at least every 3 months

iii. Compliance assessment by visual observation of hand hygiene, donning, doffing, and aseptic techniques for Category 1 and 2 at least every 6 months and Category 3 at least every 3 months

i. Achieving and/or maintaining sterility and apyrogenicity.

i. Sterilization by filtration.

ii. Methods of terminal sterilization.

iii. Methods of reduction of bioburden.

iv. Methods of reduction of pyroburden.

j. Environmental sampling (i.e., non-viable and viable air sampling, and viable surface sampling), which includes sample selection sites using facility mapping techniques, sample collection, incubation, assessment and results reading, interpretation, and corrective action and preventive action.

k. Handling and transporting components and CSPs within the non-hazardous drug compounding environment, which includes, however, may not be limited to:

i. Entering the controlled and classified environments.

ii. Transferring supplies between controlled and classified environments (i.e., Pass-throughs and doorways).

iii. Overall workflow dynamics within a controlled and classified room.

iv. Exiting the controlled and classified environments.

l. Principles of movement of materials and personnel within non-hazardous drug compounding environments.

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m. Calculations, measuring and mixing.

n. Spill control.

o. Waste management.

p. Proper use of personal protective equipment for non-hazardous drug handling and compounding.

q. Proper use of equipment and devices selected to compound CSPs, which includes, however, may not be limited to:

   i. Electronic balance.

   ii. Automated compounding devices (ACDs).

r. Documentation of the compounding process (e.g., Process Development Records leading to approved Master Formulation Records, and Compounding Records).

s. Requirements of CSP release testing, which includes, however, may not be limited to:

   i. Visual observation.

   ii. Sterility testing.

   iii. Endotoxin testing.

   iv. Filter integrity / filter breach testing.

r. Packaging, shipping and transportation of CSPs.

s. Labeling, administration and dispensing instructions for non-hazardous CSPs.

2. Compounding personnel must follow these steps in the training procedure:

   a. Read and understand the USP General Chapter 797, other applicable standards, and other relevant literature as identified by the Designated Person.

   b. Understand and interpret Safety Data Sheets (SDSs) and, if applicable, Certificates of Analysis (CoA)

   c. Read and understand procedures related to their compounding duties.

4. Competency Requirements

   1. Personnel must demonstrate competencies in the above-mentioned training requirements.

   2. Personnel must document all forms of competencies and their respective written assessments.

   3. Upon completion of the training program, the Designated Person(s) and/or Trainer must document that the personnel has been trained and successfully completed competency assessments.

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TITLE : PERSONNEL – MANAGING – PROFESSIONAL DEVELOPMENT – COMPOUNDING PRACTICES

4. **Media-Fill Testing Procedures:**

   a. If some of the starting components are nonsterile to begin with, dissolve a commercially available nonsterile soybean–casein digest powder in no sterile water to make a 3% nonsterile solution. Manipulate it in a manner that simulates nonsterile-to-sterile compounding activities.

   b. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation.

   c. Once the compounding simulation is completed and the final containers are filled with the test media, perform a **gloved fingertip** and **thumb sample** on each hand and surface sample of the direct compounding area inside the PEC. Take the samples prior to disinfecting gloves and PEC.

   d. Incubate the final containers at 20°–25° and 30°–35° for a minimum of 7 days at each temperature band to detect a broad spectrum of microorganisms. The order of the incubation temperatures must be described in the facility's SOPs. Final containers must be incubated in an incubator.

   e. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days.

5. Compliance Requirements

   1. Designated Person is responsible for the ongoing monitoring and observation of compounding activities and must include immediate corrective action if deficient practices are observed.

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VERIFICATION

1. Verify, using competency and compliance indicators/assessments, personnel performance...
    1. Routinely.
    2. In response to an error, incident, accident, complaint or adverse event.
    3. On an ongoing basis in accordance with regulatory agencies responsible for monitoring credentials and continuous professional development requirements of pharmacists and pharmacy technicians.

CORRECTIVE ACTIONS

1. Take appropriate corrective action in response to error, incident, accident, complaint or adverse event.

PREVENTIVE ACTIONS

1. Consider alteration/modification to the compounding practice's training and competency assessment program.

COMPLIANCE TEMPLATE

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TECHNOLOGICAL RESOURCES

EQUIPMENT	MANUFACTURER	MAKE	MODEL	SERIAL NUMBER	ID CODE
Medisca Equipment & Devices					

EDUCATIONAL AND SERVICE RESOURCES

AVAILABLE OFFERINGS	
LP3 Network	Medisca Compounding Services
Sterile Training - Home Studies	Medisca Formulation Support
Sterile Training - Live Event	Medisca Specialized Consultations
Self-Directed Learning Modules	Medisca Sterile Designated Person Appraisal
eLearning	

SPECIFICATION DOCUMENTS

DOCUMENT NUMBER	DOCUMENT NAME	SOURCE	DESCRIPTION

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REVISION HISTORY

REVISION NUMBER	IMPLEMENTATION DATE	TERMINATION DATE	SUMMARY OF CHANGE TO CURRENT VERSION
1	03/25/2025	03/25/2026	Adding media fill, competencies and observation assessment to SOP

REGULATORY COMPLIANCE GUIDELINES

REFERENCE SOURCE	REFERENCE CODE	REFERENCE DATE	SECTION CODE	SECTION DESCRIPTION
USP	797	01NOV23		Pharmaceutical Compounding – Sterile Preparations

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 22402
Insp # 189227

NAME	PERMIT NUMBER	DATE OF INSPECTION
TRADELINE SH, INC	29015	03/06/2025
DOING BUSINESS AS		
LOGOS PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
7543 W Waters Ave.	813-886-2800	
CITY	**COUNTY**	**STATE/ZIP**
TAMPA	HILLSBOROUGH	FL/33615

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9:00 AM - 5:00 PM
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday Y
Saturday Hours 9:00 AM - 1:00 PM	Sunday N

Registered Pharmacist / Intern / Tech

License # PS 46102	Licensee Name Raafat Habib
License Type Registered Pharmacists	
License # RPT 78453	Licensee Name Diana Zaldivar Pozo
License Type Pharmacy Tech	
License # PS 64790	Licensee Name Carlos Martinez Morejon
License Type Registered Pharmacists	
License # RPT 101384	Licensee Name Melissa Fulladolsa
License Type Pharmacy Tech	

ACS Manager

ACSMGR Raafat Habib	

Optional Information

Basic License Data - PSD

DEA Reg # [redacted]	

License Relations

Pharmacy Affiliate

HABIB, RAAFAT	License #

RX DPT MGR/COR/POR

HABIB, RAAFAT MOSSAD	License # 46102

Special Sterile Compounding

TRADELINE SH, INC	License #

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes

Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *RX Return Services*	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.] *Label Reviewed.*	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.] *01/07/2025, 10/04/2024*	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.] *Maintained in PrimeRX*	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.] *Magic Mouthwash, Topical Creams. PK Software.*	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *AmerisourceBergen*	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] *06/07/2024 End of Day*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	Yes
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages In Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Routine inspection completed with Raafat Habib. Operating requirements met.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

HODGES, PETER

Date:3/6/2025

Representative:

Raafat Habib

Date:3/6/2025

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

www.FloridaHealth.gov

File # 30299
Insp # 204341

NAME	PERMIT NUMBER	DATE OF INSPECTION
TRADELINE SH, INC		04/17/2025
DOING BUSINESS AS		
LOGOS PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
7543 W WATERS AVE		
CITY	**COUNTY**	**STATE/ZIP**
TAMPA	HILLSBOROUGH	FL/33615

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 8:30 am to 5:00 pm
Monday Y	Monday Hours 8:30 am to 5:00 pm
Tuesday Y	Tuesday Hours 8:30 am to 5:00 pm
Wednesday Y	Wednesday Hours 8:30 am to 5:00 pm
Thursday Y	Thursday Hours 8:30 am to 5:00 pm
Friday Y	Friday Hours 8:30 am to 5:00 pm
Saturday Y	Saturday Hours 9 am - 1 pm
Sunday Y	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # RPT101384	Licensee Name Melissa Fudollosa
License Type Pharmacy Tech	
License # PS64790	Licensee Name Carlos Martinez
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # [redacted]	

License Relations

Pharmacy Affiliate

HABIB, RAAFAT MOSSAD	License # 46102

RX DPT MGR/COR/POR

HABIB, RAAFAT MOSSAD	License # 46102

Special Sterile Compounding

TRADELINE SH, INC	License # 29015

INV797 - USP Sterile Compounding
(Revision 1, USP 797 2022. August 2024)
A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *Designated Person: Carlos Martinez.*	Yes

IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	Yes
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3] *The 'Beyond Use Date - Compounding practices' SOP was updated to reflect the BUD for Bulk Packages in ISO 5 PEC.*	Yes
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	N/A

C. CSP LABELING – ALL CATEGORIES

CSP LABEL REQUIREMENTS: CSP immediate container label prominently and legibly displays 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container (when space permits) or multi-dose container. Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13]	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING SOP: SOPs describe labeling procedures and are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13]	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13]	Yes

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

UNNECESSARY ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1] *Observed technician MF performing garbing process during inspection.*	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
REQUIRED PPE GARBING ORDER & STORAGE: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Pharmacy uses Avagard for hand sanitizer.*	Yes
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3]	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2]	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3] *Pharmacy uses VWR sterile wipes and alcohol.*	Yes
MATERIALS AND EQUIPMENT DISINFECTION: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1 & 9.1]	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *Daily calibration of equipment added to batch record.* **All equipment recalibrated on 4/17/25, pursuant to previous inspection on 3/24/25.*	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1] *Pharmacy maintains individual SOP for the calibration, cleaning, and maintenance of each equipment.*	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1] *Rooms last certified by MTA on 1/16/25.* *Non-HD - ISO 7* *Non-HD Ante room - ISO 7* *Non-HD Prep room - ISO 8* *HD buffer - ISO 7* *HD Ante room - ISO 7* *HD Prep room - ISO 8*	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1]	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1]	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necassary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Sections 4.2.1 & 4.5]	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *Pharmacy uses Zypher 3 Temp monitoring system and completes daily temp documentation manually.*	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the nonhazardous buffer room to anteroom and anteroom to unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *Reviewed pressure log during inspection.* **All pressures documented in range* *- Pressure during inspection -*	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC & SEC CERTIFICATION: PECs are certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.4, 4.2.6, & 5.0] *Rooms last certified by MTA on 1/16/25.* *Non-HD - ISO 7* *Non-HD Ante room - ISO 7* *Non-HD Prep room - ISO 8* *HD buffer - ISO 7* *HD Ante room - ISO 7* *HD Prep room - ISO 8*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Certification report documents 1 person present during dynamic cerification.*	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Pharmacy complete additional Smoke Pattern testing on 4/3/25 using vials instead of bags.*	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *Per policy* *- Zypher-3 monitoring system calibrated during install in October 2024.*	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. Presterilization procedures do not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions. [USP 797 Section 4.2.6] *Last certified by MTA on 1-16-25.*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0]	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3] *Pharmacy not currently compounding.* *- Operation designed to meet Category 2 Compounding.*	N/A
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Pharmacy not currently compounding.* *- Operation designed to meet Category 2 Compounding.*	N/A
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Pharmacy not currently compounding.* *- Operation designed to meet Category 2 Compounding.*	N/A

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Pharmacy compounded Semaglutide 5mg/Glycine 20mg/1ml 2 ml vials for testing on 3-7-25. Products were assigned a 45-day BUD under refrigeration.*	Yes
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Pharmacy will be terminally sterilizing oils only but plans on doing sterility testing.*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Example: Testosterone Cypionate Inj 200mg/ml (10ml) in Grapeseed Oil Inj lot 03112025@1 assigned a 45 day BUD as per SOP 'Process-Assigning-Beyond Use Dates-Compounding Practices' passed the sterility test per Pharmetric GOA*	Yes

ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *ending from Pharmetric for Semaglutide/Glycine 5mg/20mg/ml.*	N/A
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5] *Semag/utide/Glycine 5mg20mg/ml lot 03072025@2 underwent CCIT testing, Testosterone Inj did not. Firm has not dispensed CSP's yet.*	N/A
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	N/A
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	Yes
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	N/A
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2] *ompleted by Pharmetric using membrane filtration for Semag/utide/Glycine 5mg/mUG/ycine 20mg/ml -17 vials per Pharmetric paperwork, whereas Logos Pharmacy sent 70 vials.* *In progress for Testosterone Cypionate 200mg/ml (10ml) in Grapeseed Oil Inj. - Nothing was released.*	N/A
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2] *est batches were compounded : Lot 03112025@1 of Testosterone Cypionate 200mg/ml (10ml) in Grapeseed Oil Inj which was terminally sterilized resulted in 208 vials, Lot 03072025@2 Semaglutide 5mg/mL/ Glycine 20mg/ml (2 ml) inj yielding 161 vials.*	Yes
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	N/A
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *rocess-Testing-Sterility-Compounding Practices SOP has table of articles to be sent for testing to external contract lab.*	Yes
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3] *Lot 03112025@1 of Testosterone Cypionata 200mg/ml (10ml) in Grapeseed Oil Inj which was terminally sterilized underwent endotoxin testing.*	Yes
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	Yes

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	

INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. The training program equips personnel with the appropriate knowledge and training in the required skills necessary to perform their assigned tasks. [USP 797 Section 2] *Pharmacy update SOP ' Professional Development - Compounding Practices' on to in3/35.25 pursuant to previous insfection, to include Surface Sampling after Media-Fill, every 6 months.*	Yes
INITIAL DIDACTIC TRAINING & SKILLS ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1] *DP created Aseptic Techniques, Daily and Monthly Cleaning assessment.* *- Reviewed completed assessment for RPh CM and technician MF during inspection.* **Please have DP complete additional training to support the DP role.*	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *Competencies completed by CM and MF on 2-5-25, 2-6-25 and 2-7-25 respectively.*	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3] *RPh CM and technician MF successfully redid GFT, Media-fill competency on 3/26/25 with Surface sampling.*	Yes
GFT & MEDIA FILL INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3]	Yes
ONGOING CATEGORY 1 AND 2- GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *New Business.*	N/A
ONGOING CATEGORY 1 AND 2- MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3] *New Business.*	N/A
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *Competency completed in October 2024.*	N/A
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	N/A
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1] *Critical point completed October 2024.*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *SOP 'Procedure-Cleaning & Disinfecting-Compounding Facility-Compounding Practices' updated to reflect the dwell times, cleaning agents, and direction of cleaning the SEC and the PEC's - pursuant to previous inspection.*	Yes

FACILITY COMPOUNDS CATEGORY 3

ONGOING CATEGORY 3 GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	

ONGOING CATEGORY 3 ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *Per SOP 'Procedure-Sampling-Air/Surface cfu count & chemical residue-Compounding Practices'*	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *Sample size of 1000mL documented by certifier MTA.*	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *Calibrated by TRH Bioscience International Oct 21, 24.*	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *Last completed 3/7/25. To be completed in house.* *- Reviewed competency completed by technician MF on 10/20/24.*	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3] *Pharmacy uses Eagle Biomereux TSA & L& T plates.*	Yes
MEDIA INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *New Business.*	N/A
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3] *New Business.*	N/A

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused. Sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *Per SOP 'Procedure-Cleaning & Disinfecting-Compounding Facility-Compounding Practices'. and cleaning logs.* **However, observed opened Cyquanol one-step cleaner bottle without BUD dating, during inspection.*	No
DAILY PEC CLEANING & DISINFECTION WITH STERILE AGENTS: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. Sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7] *All cleaning logs updated pursuant to previous inspection.* *- Reviewed monthly cleaning documentation for the month of April, during inspection.*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7]	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7] *New business, not currently compounding daily.*	N/A
CATEGORY 1 AND 2 -MONTHLY PEC, SEC & SCA SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. SCA ceilings (if applicable) are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7] *Per cleaning policy and logs.*	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	Yes

FACILITY COMPOUNDS CATEGORY 3

WEEKLY SPORICIDAL CLEANING OF PECs & SECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's, on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to storage shelving and bins, equipment outside of PEC's, sink surfaces, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6]	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *Per 'SOP 'Procedure-Receiving-Chemicals-Compounding Practices'.*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1]	Yes
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *Pharmacy obtain Semaglutida base from Darmarica.*	Yes
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4]	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1]	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after recoipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2] *Documentation showed PK received, which was evaluated for exp date, purity, lot#, package size, wholesaler, GAS#.*	Yes
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *Time documented on CR and dry heat oven log.*	Yes

O. STERILIZATION OF CSPs - CATEGORY 2 & 3

STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2] *SOP 'Procedure-Operating-Dry Heat Sterilizer-Compounding Practices'* *Training available for MF and CM on use of Dry Heat Oven*	Yes
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Testing completed documented on 3/26/25. MFR updated to include Bubble Point Testing documented.* **Please have staff complete didactic training on Bubble Point Testing.*	Yes
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2]	Yes
CSP TERMINAL STERILIZATION SOP includes: 1) A description of CSP terminal sterilization process(es), including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization methods and equipment. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *SOP 'Procedure-Operating-Dry Heat Sterilizer-Compounding Practices' updated to include permissible load, with accompanying pictures.*	Yes
STEAM OR DRY HEAT STERILIZATION CYCLES FOR CSPs: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. CSPs sterilized vial steam are placed in the autoclave to allow steam to reach CSPs without entrapment of air. CSPs sterilized via dry heat are placed with sufficient space between materials to allow for hot air circulation. Sterilization cycle parameters (e.g., temperature, pressure, and duration) and load configuration(s) are documented. [USP 797 Section 10.3 & 10.4] *Autoclave documentation shows Dry Heat sterilization cycle for Holding Tray and Spin bars on 3/26/25.*	Yes
BIOLOGICAL INDICATOR USE: The effectiveness of steam or dry heat sterilization of CSPs is verified and documented for each sterilization run or load by using appropriate biological indicators (e.g., Geobacillus stearothermophilus for steam, Bacillus atrophaeus for dry heat) and other confirmation methods. [USP 797 Section 10.3]	Yes
STEAM & DRY HEAT CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, or dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	Yes
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each steam or dry heat sterilization cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The calibrated oven is equipped with temperature controls and a timer. [USP 797 Section 10.3 & 10.4] *Data logger print out available to ensure temp of oven reached what was required in SOP 'Procedure-Operating-Dry Heat Sterilizer-Compounding Practices'. This SOP states in "section 2 Dry Heat Sterilization 1. If dry heat sterilization is required, then it must be performed within 6 hours of completion of the CSP'. This is however, not documented on the batch record of Testosterone cypionate 200mg/ml (10ml) in Grapeseed Oil-Injection. Line 20 of the batch record states "Use oven to perform final sterilization and follow SOP 'dry heat sterilization'* *The SOP line 6 has a table for dry heat sterilization and exposure time was documented as 120 mins at 160C*	Yes

R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION & DEPYROGENATION SOP's include: 1) A description of sterilization and depyrogenation process(es) used to sterilize and/or depyrogenated compounding supplies and container closure systems, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *Per SOP 'Procedure-Operating-Dry Heat sterilizer-Compounding Practices'* *-Training for technician MF and RPh CM on use of Dry Heat Oven documented.*	Yes
DEPYROGENATION VIA DRY HEAT: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1 & USP 1228.4]	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are sterilized via a validated sterilization method and cycle: these items are also depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section 10 & 10.1] *Per SOP 'Operation Depyrogenating Oven'.* *- Pharmacy Depyrogenates beaker, tweezers, holding trays and spin bars cylinders by rinsing.*	N/A
DEPYROGENATION PROCESS VALIDATION: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using Endotoxin Challenge Vials (ECVs) to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the cycle parameters . Cycle verifications are documented. [USP 797 Section 10.1] *Per SOP 'Procedure-Operating-Depyrogenation Oven-Compounding Practices' SOP states annually and completed by Pharmetric using CRV ECV vials for a 5. 1 Jog reduction.*	Yes
STERILIZATION CYCLE VALIDATION: When performed onsite, the efficacy of sterilization cycles used for supplies or container closure systems are established and documented. Each sterilization run or load is verified and documented by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 9.3.1 & USP 1229] *Pharmacy previously terminally sterilized Testosterone Cypionate 200mg/ml (10ml) in Grapeseed Oil Inj. BI strips were incubated at incorrect temperature of 34C.* *- SOP 'Dry Heat Sterilizer' updated to correct temperature variation by stating per manufacturer instruction. DP provided a copy of Bionova instructions from his records.*	N/A

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient and any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *Per SOP 'Patient-Processing-Compounding Records-Compounding Practices'.* *- Reviewed MFR with updates during inspection.*	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *Pharmacy in the process of completing internal stability study.* *- Time zero completed on 3/7/25 which was at 97.4%* *- Time 45 on 4/21/25*	N/A
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2] *Pharmacy updated MFR for Semaglutide 5mg/mVGlycine 20mg/ml (2ml) Injectable testing 3/7/25 with under Delayed Visual Inspection, to include "Absence of leak".*	N/A
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *Run number for Testosterone lot 03112025@1, terminally sterilized on 3/11/25, was log but not the batch record.* *- MFR was updated to include the Run number and date on 3/26/25, pursuant to previous inspection.*	Yes

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *Per SOP 'Process-Performing-Visual Inspections-Compounding Practices'.*	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1]	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *MFR updated to include Delayed Visual Inspection.*	Yes
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1]	Yes
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1] *Pharmacy completed CAP for incorrect documentation of 7 X 2ml vials incorrectly stated on testing COA for Method Suitability for Sterility determination by Pharmetric.* *- Reviewed updated COA from PharMetrics with correct volume, completed on 3/24/25, and CAPA completed by pharmacy.*	Yes

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. [USP 797 Sections 9.3 & 19.1] *Temperature on Zypher-3 continuous monitoring software. Temperature manually documented daily when open.*	Yes
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2]	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *Per SOP 'Process-Shipping-Compounded Sterile Preparations-Compounding Practices'.* *- New business; not currently shipping but plan UPS overnight shipping.*	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

OA/OC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (OC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *Per OP 'Managing QA/QC Programs Compounding Practices'.*	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3]	Yes
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *Pharmacy has ADR log and complaint log.*	N/A
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18] *Per OP 'Performing-Recall (Inventory and Preparations-Compounding Practices'.*	N/A
ANNUAL SOP & QA/QC COMPLIANCE REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 17 & 18] *New business.*	N/A

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4] *Designated Person: Carlos Martinez.*	Yes
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8] *Per SOP 'Personnel-Managing-Professional Development-Compounding Practices (HD)'* *SDS yellow binder*	Yes
LIST OF HAZARDOUS DRUGS & ASSESSMENT OF RISK: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must documents what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation considerations. The HD drug list & AOR is reviewed at least every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2] *AOR done for Testosterone - Done Nov 26, 2024.*	Yes
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1] *Pharmacy has a USP 800 storage room.*	Yes
HD HANDLING, RECEIPT & STORAGE SOPs: SOPs are created and followed for the safe handling of HDs used by the facility. [USP 800 Section 17] *Per SOP 'Procedure-Receiving-Chemical-Compounding Practices' -See traditional area for receiving with Preempt wipes and USP 800 storage room where items removed from shipping cartons are transferred to.*	Yes
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, storage, and sterile compounding of HDs. [USP 800 Section 5] *Please update HD receiving area to include spill kit, decontamination agents, and decontaminating log/documentation.*	Yes
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2] *HD stored in ISO 8 prep area.*	Yes
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	N/A
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated has 30 ACPH, and negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Section 5.3.2 Table 3] *Per MTA Jan 16, 2025, Chemo room documented ACPH was 45. Only pressures documented are for the negative pressure HD rooms.*	Yes

C-SEC ACCESS: The Ante Room used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. Alternatively, a negative-pressure HD buffer entered exclusively through a positive pressure non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2] *HD Ante room has documented ACPH of 34 from Jan 16, 2024 MTA report.*	Yes
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	Yes
C-PEC LOCATION, VENTING, & OPERATION: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. C-PECs operate continuously if supplying some or all the negative pressure in the C-SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3.2]	Yes
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free and two pair of chemotherapy gloves are donned per SOP. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding garment. When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. Reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	Yes
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	Yes
HD TRAINING & COMPETENCY ASSESSMENT: Personnel who handle HDs are trained and demonstrate competency initially before independently handling HDs, annually, and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17] *Critical point training completed.*	Yes
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	Yes
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	Yes
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 5.3.2 and Table 3]	N/A
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): Areas where HDs are handled and all reusable equipment and devices are deactivated/decontaminated, and cleaned. Sterile compounding areas and devices are subsequently disinfected. Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15] *D/D/C/D documentation updated to include cleaning with Sterile 70% Isopropyl Alcohol is used after Peridox.*	Yes
D/D/C/D TRAINING & PPE REQUIREMENTS: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. [USP 800 Section 15]	Yes
C-PEC D/D/C/D: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. The area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2] *Cleaning checklist updated to include the cleaning of under worktray.*	Yes
HD LABELING, PACKAGING, TRANSPORT & SPILLS HANDLING: Facility follows SOP for the labeling, handling, packaging, and transport of HDs which addresses the prevention of spills/exposures, training for exposure, and spill handling. HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Section 11 & 11.2] *Labels for Testosterone updated to include CIII schedule, HD.* **Please include dosage form on Testosterone labels.*	Yes
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16] *Spill kit located in HD prep room.* ***Please add a spill kit to HD handling area.*	Yes

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	

Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(I) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Z. Miscellaneous

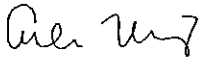
BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	
ALLERGENIC EXTRACTS: Licensed allergenic extracts are mixed and diluted to prepare prescription sets for administration to patients. A prescriptions set is a vial or set or vials of premixed licensed allergenic extracts for subcutaneous immunotherapy that have been diluted with an appropriate diluent for an individual patient. Compounding allergenic extracts 1) minimally complies with all aspects of USP <797> Section 21; 2) involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and 3) manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials. If these conditions are not met, compounding of allergenic extracts follows all aspects of USP <797>. [USP 797 Sections 1.1.2 and 21]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

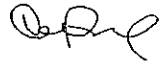
MURRAY, CHARLENE



Date:4/17/2025

Representative:

Carlos Martinez



Date:4/17/2025

Your license number is PH 29015.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
NOVEMBER 14, 2024	PH 29015	143892

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2027**

TRADELINE SH, INC
Logos Pharmacy
7543 W WATERS AVE.
TAMPA, FL - 33615

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
NOVEMBER 14, 2024	PH 29015	143892

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

TRADELINE SH, INC
Logos Pharmacy

Expiration Date: **FEBRUARY 28, 2027**

REGISTRANT SIGNATURE

Your license number is PH 35710.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
04242025	PH 35710	155412

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Special Sterile Compounding

EXPIRATION DATE: **FEBRUARY 28, 2027**

TRADELINE SH, INC
LOGOS PHARMACY
7543 W WATERS AVE
TAMPA, FL - 33615

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DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
04242025	PH 35710	155412

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

TRADELINE SH, INC
LOGOS PHARMACY

Expiration Date: FEBRUARY 28, 2027

REGISTRANT SIGNATURE

June 23, 2025

Logos Pharmacy
7543 W Waters Ave
Tampa, FL 33615

RE: License Certification for Tradeline Sh, Inc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH29015
ORIGINAL CERTIFICATION:	04/07/2015
EXPIRATION DATE:	02/28/2027
CURRENT STATUS OF LICENSE:	Clear,
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Community Pharmacy, Schedule Ii & Iii

To expedite the verification process, the above format is the standard format for all license certifications. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gwendolyn B. Freeman

Gwendolyn B. Freeman
Operations and Management Consultant Manager

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT5315622	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-05-2023

TRADELINE SH, INC.
DBA LOGOS PHARMACY
7543 W WATERS AVE
TAMPA, FL 33615

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT5315622	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-05-2023

TRADELINE SH, INC.
DBA LOGOS PHARMACY
7543 W WATERS AVE
TAMPA, FL 33615

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FP4807927 ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Pharmacorr Sterile, LLC

Physical Address: 1500 SE 66th Street

City: Oklahoma City State: OK Zip: 73149

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 833-327-9567 Toll Free # (NAC 639.708, NRS 639.23286): 833-327-9567

Fax: 833-327-9568 Contact Email: jessica.mcmakin@pharmacorrsterile.com

Website: www.pharmacorrsterile.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jessica McMakin

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Carla Hawkins	NV Pharmacist Registration #: 24625
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Pharmacorr Sterile, LLC

Business Name: Pharmacorr Sterile, LLC

Business Address: 1500 SE 66th Street

City: Oklahoma City State: OK Zip: 73149

Telephone: 833-327-9567 Email: jessica.mcmakin@pharmacorrsterile.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Pharmacist (title) for Pharmacorr Sterile (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jessica McMakin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/17/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Faigy Goldberger, Managing Member

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

7/17/25

Date

Board Use Only	Date Received: 8/14/25	Amount: $500 ck 300040

OFFICE OF THE SECRETARY OF STATE

STATE OF OKLAHOMA

CERTIFICATE OF GOOD STANDING
DOMESTIC LIMITED LIABILITY COMPANY

I, THE UNDERSIGNED, Secretary of State of the State of Oklahoma, do hereby certify that I am, by the laws of said state, the custodian of the records of the state of Oklahoma relating to the right of certain business entities to transact business in this state and am the proper officer to execute this certificate.

I FURTHER CERTIFY that PHARMACORR STERILE LLC whose registered agent is CT CORPORATION SYSTEM, with its registered office at 1833 SOUTH MORGAN ROAD OKLAHOMA CITY 73128 USA Oklahoma is a Domestic Limited Liability Company duly organized and existing under and by virtue of the laws of the state of Oklahoma and is in good standing according to the records of this office. This certificate is not to be construed as an endorsement, recommendation or notice of approval of the entity's financial condition or business activities and practices. Such information is not available from this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and affixed the Great Seal of the State of Oklahoma, done at the City of Oklahoma City, this 24th, day of July, 2025.

Secretary Of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Pharmacorr Sterile

Pharmacy/Wholesaler License # (if applicable) pending this application

Physical Address 1500 SE 66th Street

City Oklahoma City State OK Zip 73149

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 833-327-9567 Website www.pharmacorrsterile.com

Licensing Company Email jessica.mcmakin@pharmacorrsterile.com

Section 2: Personal Information

First Jessica Middle Lee Last McMakin

Alias(es, nicknames, name changes, etc.) Jessica Yvonne Lee

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Addre[redacted]

City [redacted] State [redacted] Zip [redacted]

Telepho[redacted] Ema[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Oklahoma College of Pharmacy		08/2006-06/2010	
Address	City	State	Zip
1110 N. Stonewall Ave	Oklahoma City	ok	73117
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Oklahoma		08/2004-05/2006	
Address	City	State	Zip
660 Parrington Oval	Norman	OK	73019
Diploma/Degree obtained, if any			
Undergrad/Pre-pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Central Oklahoma		08/2003-12/2016	
Address	City	State	Zip
100 N. University Drive	Edmond	ok	73034
Diploma/Degree obtained, if any			
Undergrad/Pre-pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Oklahoma City Community College		12/2004-12/2005	
Address	City	State	Zip
7777 S. May Ave	Oklahoma City	ok	73159
Diploma/Degree obtained, if any			
Undergrad/Pre-pharmacy			

School Name		From - To (MM/YY – MM/YY	
Edmond Memorial High School		08/2000-05/2004	
Address	City	State	Zip
1000 E. 15th St	Edmond	ok	73013
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2023-Present	[redacted]			
08/2022-06/2023				
02/2022-08/2022				
09/2021-08/2022				
09/2018-9/2021				
07/2017-09/2018				
07/2015-07/2017				
11/2011-07/2015				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Pharmacorr Sterile			06/2024-Present	
Business Address		**City**	**State**	**Zip**
1500 SE 66th St		Oklahoma City	ok	73149
Phone	**Title**		**Number of Employed Hours**	
1-833-327-9567	Pharmacist-in-charge		2240	

Description of Duties
Ensure compliance with USP <797>, USP <800>, and applicable state/federal laws. Supervise and train pharmacy staff in aseptic technique and cleanroom procedures. Oversee compounding, labeling, packaging, and dispensing of sterile preparations. Maintain and review environmental monitoring, cleanroom certification, and quality assurance recordsConduct regular audits of compounding processes and documentation.Develop and maintain Standard Operating Procedures (SOPs). Respond to and investigate quality deviations, out-of-spec results, and complaints.Coordinate with purchasing and inventory to ensure availability of sterile compounding supplies

Business Name			From - To (MM/YY – MM/YY)	
The Apothecary Room			02/2023-Present	
Business Address		**City**	**State**	**Zip**
2000 E. 15th St Unit 100B		Edmond	OK	73013
Phone	**Title**		**Number of Employed Hours**	
405-696-4777	Pharmacist-in-charge/Owner/PRN Pharmacist		2720	

Description of Duties Ensure compliance with USP <795>, <800>, DEA, FDA, and Board of Pharmacy regulations. Supervise compounding of non-sterile compounding. Oversee pharmacy operations, including staffing, inventory, workflow, and quality assurance.Train and manage pharmacists, technicians, and support staff. Maintain and implement Standard Operating Procedures (SOPs). Manage patient safety, prescriber communication, and clinical consultations. Oversee business operations such as budgeting, purchasing, marketing, and customer service. Represent the pharmacy during inspections and ensure readiness for audits or regulatory reviews

Business Name			From - To (MM/YY – MM/YY)	
Pharmacorr			08/2022-6/2024	
Business Address		**City**	**State**	**Zip**
7400 Plaza Mayor Blvd		Oklahoma City	OK	73149
Phone	**Title**		**Number of Employed Hours**	
405-488-3000	Staff Overnight Pharmacist		1000	

Description of Duties
Data entry of prescription orders for various prison systems and verification of orders. Final check of filled orders and receiving inventory and running a few reports.

Business Name			From - To (MM/YY – MM/YY)	
Preferred Rx			02/2017-08/2022	
Business Address		**City**	**State**	**Zip**
1111 N. Lee Ave Suite 100		Oklahoma City	OK	73103
Phone	**Title**		**Number of Employed Hours**	
405-609-1911	Pharmacist-in-charge/PRN Pharmacist		5604	

Description of Duties Ensure compliance with Board of Pharmacy, DEA, HIPAA, and other applicable laws and regulations. Oversee prescription processing, dispensing, & counseling to ensure accuracy and patient safety. Supervise, manage, train pharmacy staff, including pharmacists, technicians, & clerks. Maintain accurate inventory control, handle controlled substances per DEA regulations, & manage ordering and returns. Provide clinical services such as medication therapy management (MTM) & patient education. Ensure proper documentation, record-keeping, and adherence to Standard Operating Procedures. Ensure the pharmacy is always inspection-ready.

Business Name			From - To (MM/YY – MM/YY)	
Ralph's Family Pharmacy			02/2017-04/2020	
Business Address		**City**	**State**	**Zip**
1101 NW 178th St Suite A		Edmond	ok	73013
Phone	**Title**		**Number of Employed Hours**	
405-285-2600	Staff Pharmacist		6000	

Description of Duties Review, interpret, and verify prescriptions for accuracy, safety, and appropriateness. Dispense medications and counsel patients on proper use, side effects, and drug interactions. Ensure compliance with state and federal regulations, DEA guidelines, and HIPAA standards. Maintain accurate patient records and documentation.Provide immunizations, medication therapy management (MTM), and other clinical services as authorized. Monitor inventory and ensure proper storage, handling, and disposal of medications, including controlled substances. Assist in supervising and mentoring pharmacy technicians and support staff Compounding.

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Cedar Ridge Behavioral Hospital/Bethany Behavioral Health - through Comprehensive Pharmacy Services		01/2015-02/2017	
Business Address	**City**	**State**	**Zip**
6501 NE 50th St/ 7600 NW 23rd St	OKC/Bethany	OK	73141/73008
Phone	**Title**	**Number of Employed Hours**	
405-605-6111	Director of Pharmacy	4480	

Description of Duties Oversee all pharmacy operations, including medication procurement, storage, compounding, & distribution. Ensure compliance with The Joint Commission (TJC), CMS, state and federal regulations, & hospital policies. Lead a team of pharmacists and technicians, ensuring proper staffing, training, and performance management. Collaborate with psychiatrists, nurses, and other clinicians on medication management and treatment planning. Develop and maintain formulary management, drug utilization reviews, and monitor psychotropic prescribing trends. Implement & monitor medication safety protocols, especially regarding high-alert and controlled substances.Manage pharmacy budget, inventory control, and cost-containment strategies. Participate in interdisciplinary committees, including Pharmacy & Therapeutics (P&T) and Quality Improvement.Support staff education on psychiatric medications, adverse effect monitoring, and drug interactions.

Business Name		From - To (MM/YY – MM/YY)	
Thrifty Pharmacy		08/2013-01/2015	
Business Address	**City**	**State**	**Zip**
203 S. Santa Fe Ave	Edmond	OK	73003
Phone	**Title**	**Number of Employed Hours**	
405-715-4405	Pharmacist-in-Charge	2880	

Description of Duties Ensure compliance with Board of Pharmacy, DEA, HIPAA, and other applicable laws and regulations. Oversee prescription processing, dispensing, & counseling to ensure accuracy and patient safety. Supervise, manage, train pharmacy staff, including pharmacists, technicians, & clerks. Maintain accurate inventory control, handle controlled substances per DEA regulations, & manage ordering and returns. Provide clinical services such as medication therapy management (MTM) & patient education. Ensure proper documentation, record-keeping, and adherence to Standard Operating Procedures. Ensure the pharmacy is always inspection-ready. Long term care facility packaging and order management working with providers.

Business Name		From - To (MM/YY – MM/YY)	
Walmart Pharmacy		11/2004-08/2013	
Business Address	**City**	**State**	**Zip**
6100 W. Reno Ave (Various other locations too)	Oklahoma City	OK	73127
Phone	**Title**	**Number of Employed Hours**	
405-491-0320	Pharmacist-in-charge/Staff Pharmacist/Grad intern/Intern/Technician/Cashier	>6000+	

Description of Duties Supervise pharmacy operations, including prescription processing, inventory control, and customer service. Ensure compliance with state and federal pharmacy laws, DEA regulations, and company policies. Oversee and support the pharmacist and technician team, including scheduling, training, and performance management. Monitor and maintain proper storage, handling, and documentation of controlled substances. Provide clinical services, including immunizations, medication therapy management (MTM), and patient counseling. Manage inventory, order medications and supplies, and minimize stockouts and expired products. Ensure accurate recordkeeping and maintain readiness for regulatory inspections. Track pharmacy performance metrics (e.g., wait times, prescription volume, adherence programs).Resolve patient concerns or insurance issues and ensure high levels of customer satisfaction. Collaborate with corporate or ownership teams to meet financial and operational goals.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Jessica McMakin, **certify that as the designated representative for**

Pharmacorr Sterile, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jessica McMakin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/23/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica McMakin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/23/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Oklahoma, ss. County of Oklahoma

I, Jessica McMakin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/23/25

Date

Subscribed and Sworn to before me this 23rd day of July 2025.

Jacqueline N. Konarik

Notary Public Signature

JACQUELINE N. KONARIK NOTARY # 06009396 EXP. 09/25/26 PUBLIC STATE OF OKLAHOMA (Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PHARMACORR STERILE, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PENDING APPLICATION

Physical Address 1500 SE 66TH STREET

City OKLAHOMA CITY State OK Zip 73149

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 833-327-9567 Website WWW.PHARMACORRSTERILE.COM

Licensing Company Email jessica.mcmakin@pharmacorrsterile.com

Section 2: Personal Information

First _____ Middle _____ Last _____

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

2600

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)
Bais Rochel of Satmar		09/1982 – 10/1984
Address	**City**	**State / Zip**
62 Harrison Ave	Brooklyn	NY 11211
Diploma/Degree obtained, if any		

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2000 – 08/25	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
United Staffing Solutions			2020 - 2025	
Business Address		**City**	**State**	**Zip**
1385 Broadway		New York	NY	10018
Phone	**Title**			
800-972-9725				
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Faigy Goldberger

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-31-2025

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of New York

I, Faigy Goldberger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/31/2025

Date

Subscribed and Sworn to before me this 31 day of July, 2025.

Notary Public Signature

YECHIEL LEHRFIELD
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01LE6385614
Qualified in RICHMOND County
Commission Expires JANUARY 7, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Pharmacorr Sterile

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 1500 SE 66th St

City: Oklahoma City State: OK Zip: 73149

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 1-833-327-9567 Toll Free # (NAC 639.708, NRS 639.23286): 1-833-327-9567

Fax: 1-833-327-9568 Contact Email: jessica.mcmakin@pharmacorrsterile.com

Website: www.pharmacorrsterile.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jessica McMakin

Supervising/Managing Pharmacist NV Pharmacist Registration #: Carla Hawkins 24625

Name of Designated Person(s) as defined by revised USP-797 guidelines: Jamie Russell, James Mangham, Jessica McMakin

Email of Designated Person(s): Jamie.Russell@pharmacorrsterile.com James.Mangham@pharmacorrsterile.com

Telephone of Designated Person(s) [redacted] (all cell numbers)

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 07/10/2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Once weekly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Semaglutide/Niacinamide SQ Injection
Semaglutide/Methylcobalamin SQ injection
Tirzepatide/Niacinamide SQ injection
Tirzepatide/Methylcobalmin SQ Injection f
NAD+ 200mg/mL injection 5 to 10 mL vial with preservative SQ or IM

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Pkwy #546

City: Oklahoma City State: OK Zip: 73104

Telephone: 405-271-1144

13. What is your procedure for visual inspection of compounded sterile products?

All compounds undergo visual inspection by a pharmacist before sterilization during compounding and after sterilization while product is waiting for endotoxin, sterility and potency testing. Once results are back, batch is removed from quarantine and visually inspected for a 3rd time by a pharmacist. All of these checks are documented in Pharmacy Keeper. Each final dosage form is checked by a pharmacist 2 times, prior to dispensing (once when labeling dosage form and when final checking the prescription). The inspections are conducted under adequate lighting using both white and black contrasting backgrounds to detect visible particulate matter, discoloration, cloudiness, container defects, or leakage with a box light and magnifier glass. We examine the solution for floating particles or precipitates, ensuring the product appears clear and consistent with expected characteristics. Container integrity, labeling accuracy, and proper sealing must also be verified by a pharmacist. Any CSP that fails inspection must be rejected, quarantined, and investigated, with findings documented. We also reverify if a prescription is not sent out that same day prior to selling if filled more than 24 hours prior.

14. How often do you perform glove fingertip and medial fill testing?

Initially we do 3 sets for all new employees and then every 3 months for hands on compounding personnel and every 6 months for those who only oversee it or are ancillary and do not go in lab often.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

See SOP 1.6) Orientation and Training

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See SOP 1.3 and 1.4 Attached

17. Who performs the sterile compounding process at your facility?

Currently all employees are involved in the compounding process. We have 4 Technicians and 2 pharmacists

18. Who is responsible and accountable for the sterile compounding process at your facility?

James Mangham, Pharmacy Technician/Quality Assurance/Compliance officer/DP, Jamie Russell, Pharmacy Technician- Head Designated Person, Jessica McMakin, Pharm.D. - PIC/DP

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

We have completed temperature studies on our shipping containers and have modified as the seasons have changed. As it got warmer we adjusted our container and retested it, added dry ice and multiple ice packs to ensure in the summer months, everything is getting there at proper temperature. We also use spot-c labels for patients to verify it did not go over a certain temperature.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	☐ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☐ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?	
6. What is the frequency for using sporicidal agents?	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐Yes ☐No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐Yes ☐No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Lee McMakin

Name of Person who Completed the Form

Pharmacist In Charge

Title

Signature (copies or stamps not accepted)

07/23/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for cleaning and disinfection of non-HD sterile compounding areas at Pharmacorr Sterile to ensure quality of compounded preparations and safety of personnel.

2.0 Definitions

2.1 Cleaning removes organic and inorganic matter. Use one-step disinfectant cleaner on surfaces. Use Alconox products for glassware and utensils (Alcotabs (or equivalent) in the dishwasher and Liquinox (or equivalent) for handwashing).

2.2 Disinfection destroys microorganisms. Use one-step disinfectant cleaner on surfaces. Follow with 70% IPA on hoods and work surfaces.

3.0 Procedure

3.1 This procedure applies to all personnel involved with cleaning activities.

3.2 Agents selected must be appropriate for the type of contaminant, location, and surface materials. All disposable materials must be discarded in appropriate waste containers. No cleaning step may be performed when compounding activities are occurring. Ensure adequate dwell times.

3.3 Personnel must be garbed appropriately for the area. See SOP 1.40 Sterile Compounding Area for garbing requirements and frequency of activities.

3.4 ISO-Classified Areas

3.4.1 All cleaning materials, such as wipers, sponges, and mops used in ISO-classified areas must be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the Non-HD ISO-classified area and must not be removed from this area except for disposal. Agents and wipers used in ISO Class 5 must be sterile. Agents and wipers used in ISO Class 7 or 8 should be sterile.

3.4.2 Non-HD anteroom and (positive pressure) buffer room and all reusable equipment must be cleaned and disinfected. A disinfectant with sporicidal activity must be used at least monthly. Category 3 compounding requires more frequent

use. See SOP 1.40 Sterile Compounding Area. Floor must have a designated mop labeled 'Floor'. Floor mops may be used in both the buffer room and anteroom, but only in that order.

3.5 All personnel who perform cleaning and disinfection activities must be trained in appropriate procedures to protect themselves and the environment from contamination.

3.6 See Attachment 1 for Cleaning and Disinfecting Agents in Use.

4.0 References

4.1 Oklahoma Board of Pharmacy Laws and Rules

4.2 USP <797> Pharmaceutical Compounding – Sterile Preparations (2023)

5.0 Attachments

5.1 Attachment 1 Cleaning and Disinfecting Agents in Use

Version	Effective Date	Approved by	Description of Change
1	11-04-24		New SOP

Verified by:	Title	Signature	Date
Jessica McMakin	Pharmacist in Charge		
Approved by:			
Jamie Russell	Designated Person		
Approved by:			
James Mangham	QA/QC Officer		

Deactivating, Decontaminating, Cleaning and Disinfecting Agents in Use

Chemical	Action	Function	Active Ingredients	Dwell Time	Notes
Curis Solution	Sporicidal/Decontaminant	Decontamination	Hydrogen Peroxide		
Sterile ProSat Alcohol Swabs	Disinfectant	Disinfectant	70% IPA	Until Dry	
Sterile ProSat Alcohol Wipes(Contec)	Disinfectant	Disinfectant	70% IPA	Until Dry	
Sterile ProSat Cyquanol Wipes(Contec)	Fungicide, Bactericide, Virucide, Tuberculocide	1 Step Disinfectant Cleaner	Quaternary Ammonium, Ethyl Alcohol	1 Minute	
Sterile Cyquanol Solution(Contec)	Fungicide, Bactericide, Virucide, Tuberculocide	1 Step Disinfectant Cleaner	Quaternary Ammonium, Ethyl Alcohol	1 Minute	
Sterile PeridoxRTU Solution	Fungicide, Bactericide, Virucide, Tuberculocide, Mold Killing, Sporicide	1 Step Disinfectant Cleaner	Hydrogen Peroxide, Peracetic Acid	3 Minutes	
Spectrum Antibacterial Foaming Hand Soap	Cleaner	Cleaner	Benzalkonium Chloride	At least 30 seconds	
Spectrum Foaming Hand Sanitizer	Disinfectant	Sanitizer	70% Ethyl Alcohol	Until Dry	
Micro-Kill D1 Plus Germicidal Wipes(Medline)	Germicidal, bactericide, Virucide, Tuberculocide, Fungicide	1 Step Disinfectant Cleaner	Dodecylbenzenesulfonic Acid	75 Seconds	
Pre-Empt Plus Wipes	Fungicide, Bactericide, Virucide, Tuberculocide	1 Step Disinfectant Cleaner	Accelerated Hydrogen Peroxide	1 Minute	
Pre-Empt Plus RTU Solution	Fungicide, Bactericide, Virucide, Tuberculocide	1 Step Disinfectant Cleaner	Accelerated Hydrogen Peroxide	1 Minute	
PeridoxRTU Solution	Fungicide, Bactericide, Virucide, Tuberculocide, Mold Killing, Sporicide	1 Step Disinfectant Cleaner	Hydrogen Peroxide, Peracetic Acid	3 Minutes	
Spectrum Gel Hand Sanitizer	Disinfectant	Sanitizer	70% Ethyl Alcohol	Until Dry	
DAWN Platinum Plus Power-Wash	Cleaner	Soap		N/A	
Hibiclens	Cleaner	Soap	Chlorhexidine	N/A	
The Safety Direction Lens Wipes	Disinfectant	Disinfectant	70% IPA	Until Dry	
5 gallon 70% Isopropyl Alcohol Solution	Disinfectant	Disinfectant	70% IPA	Until Dry	
Sterile 1 gallon 70% Isopropyl Alcohol(VWR)	Disinfectant	Disinfectant	70% IPA	Until Dry	
Dynarex Sterile Alcohol Prep Pads	Disinfectant	Disinfectant	70% IPA	Until Dry	This product is exempt from SDS.

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for the sterile compounding area at Pharmacorr Sterile to ensure quality of compounded preparations and safety of personnel.

2.0 Definitions

2.1 Anteroom An ISO Class 8 or better transition area between the Buffer Room and non-classifed area.

2.2 Buffer Room An ISO Class 7 or better area containing the Primary Engineering Control.

2.3 CFU Colony forming unit

2.4 Cleanroom See Buffer Room.

2.5 COA Certificate of Analysis

2.6 Primary Engineering Control (PEC) Laminar airflow workbenches (LAFWs), Biological Safety Cabinets (BSCs), or Compounding Aseptic Isolators (CAIs) which provides an ISO Class 5 environment for sterile compounding.

2.7 ACPHs Air changes per hour.

3.0 Procedure

3.1 This procedure applies to all personnel involved with sterile compounding activities.

3.1.1 Pharmacy performs Category 2 and Category 3 sterile compounding.

3.1.2 Pharmacy does not perform HD sterile compounding.

3.2 Pharmacorr Sterile must perform sterile compounding in accordance with USP Chapter 797 and standards of practice adopted by the Oklahoma Board of Pharmacy and by national practices and standards adopted by government and non-government standard setting organizations.

3.3 Only authorized personnel must be allowed in the sterile compounding area.

No food, drinks (including water), cosmetics, or personal items are permitted sterile compounding areas. Only electronics essential to compounding are permitted.

3.4 Individuals entering the sterile compounding area must maintain appropriate personal hygiene and evaluate whether they have a personal risk of potentially contaminating the compounding environment and CSP (rashes, recent tattoos, oozing sores, conjunctivitis, active respiratory infection). These conditions must be reported to the designated person who is responsible for evaluating whether these individuals should be excluded from working in compounding areas until their conditions have resolved.

3.5 Sterile compounding personnel must be garbed according to task. Garb must include low-lint garb including scrubs, gowns, shoe covers, head cover, beard cover (if applicable), mask or respirator, and eye protection (as needed). Sterile gloves must be worn while compounding. The designated person may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.

3.5.1 Before entering the sterile compounding area personnel must change into provided cleaned scrubs. All personnel must wipe eyeglasses and remove.

3.5.1.1 Personal outer garments including bandanas, coats, hats, jackets, scarves, sweaters, vests, etc.

3.5.1.2 Cosmetics.

3.5.1.3 Hand, wrist and other visible jewelry. Cover any jewelry that cannot be removed.

3.5.1.4 Ear buds and headphones

3.5.1.5 Nail polish and artificial nails. Nails must be clean and neatly trimmed.

3.5.2 Personnel must don garb from dirtiest to cleanest starting with donning shoe covers while crossing over the line of demarcation, then head cover, beard cover (if applicable), and mask before hand washing.

3.5.2.1 Hand washing must be performed by first cleaning fingernails under running water using a disposable nail pic then vigorously washing all surfaces of hands and forearms up to the elbow for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) followed by thorough rinsing and drying.

3.5.2.2 After hand washing, sanitize hands with an alcohol-based hand rub them don sterile gloves. Don a sterile coverall (without letting anything but the bottom of the foot portion touch the floor. Don goggles ensuring that all skin is covered.

3.5.2.3 Wipe gloves with sterile 70% isopropyl alcohol and allow to dry. Don a second set of sterile gloves. Wipe outer gloves with sterile 70% isopropyl alcohol and allow to dry. When performing cleaning or pre-sterilization activities before compounding in the ISO-5 PEC, don a new pair of outer sterile gloves before compounding in the ISO-5 PEC.

3.5.2.4 Wipe outer gloves with sterile 70% isopropyl alcohol and allow to dry before entering the ISO Class 5 PEC to compound and as needed throughout the compounding process and whenever nonsterile surfaces are touched.

3.5.2.5 Personnel must continuously wear all sterile garb in buffer rooms used for Category 3 compounding. No bare skin may be exposed.

3.5.2.5 When compounding is complete, all disposable garb must be removed and discarded.

3.6 Sterile compounding must be performed in a certified ISO Class 5 primary engineering control situated in a certified ISO Class 7 or better buffer room. See SOP 1.24 Certification Requirements. ISO Class 5 hood must run for a minimum of 30 minutes before use.

3.6.1 Temperature in ISO classified rooms should be 20°C (68°F) or cooler and must not exceed 25°C (77°F). Humidity should be at or below 60%. Document temperature and humidity each day compounding is performed on the Daily Temperature, Humidity, and Pressure Log in Pharmacy Keeper. Document excursions per SOP 6.20.

3.6.2 Pressure must meet requirements of SOP 1.22 EM Pressure. Document pressures each day compounding is performed per SOP 1.22 EM Pressure. Document on the Daily Temperature, Humidity, and Pressure Log in Pharmacy Keeper. Document excursions per SOP 6.20.

3.7 Sterile compounding area must be clean and organized to prevent mix-ups or cross-contamination. Document daily cleaning (including agents used) each day compounding occurs on Daily Room Cleaning and/or Beginning of Shift & Hood and Ending of Shift & Hood Cleaning activities in Pharmacy Keeper. See SOP 1.30 Cleaning Procedures for current agents in use.

3.7.1 Presterilization activities (weighing and mixing) must be performed in a containment ventilated enclosure (CVE) located in an ISO-classified room.

3.7.2 ISO-classified primary engineering controls must be cleaned and disinfected at the beginning of each day of use, when spills occur, and when contamination is known or suspected. In addition, sterile 70% IPA must be applied to the horizontal work surface (and allow to dry) before compounding each batch and at least every 30 minutes. If the compounding process takes more than 30 min, compounding must not be disrupted, and the work surface must be wiped immediately after compounding. Document daily cleaning and disinfection on Daily Room Cleaning and/or Beginning of Shift & Hood and Ending of Shift & Hood Cleaning activities in Pharmacy Keeper. An agent with sporicidal activity must be used at least weekly in ISO Class 5 PECs used for Category 3 compounding.

3.7.3 CVEs must be cleaned and disinfected at the beginning and end of each day of use, when spills occur, and when contamination is known or suspected. The horizontal work surface must be cleaned and disinfected before compounding each batch. Document in Beginning and Ending Shift hood cleaning activities in Pharmacy Keeper.

3.7.4 Buffer room(s) and anteroom

3.7.4.1 Work surfaces, pass-throughs, high touch areas, sink, and

floors must be cleaned and disinfected each day compounding occurs. Floors must have a dedicated mop and be cleaned and disinfected from cleanest to dirtiest starting in the buffer room. Trash must be removed daily. Document daily cleaning and disinfection in Daily Room Cleaning Activity in Pharmacy Keeper. An agent with sporicidal activity must be used at least weekly on work surfaces, pass-throughs, and floors for Category 3 compounding. Document in Weekly Room Cleaning Activity in Pharmacy Keeper.

3.7.4.2 Monthly cleaning and disinfection must be performed from cleanest to dirtiest starting in the buffer room. Monthly cleaning must include all surfaces including ceiling, walls, exterior of equipment and fixtures, storage, etc. Document monthly cleaning and disinfection on Monthly Room Cleaning in Pharmacy Keeper. A disinfectant with sporicidal activity must be used.

3.7.4.3 Storage areas outside of the cleanroom must be cleaned and disinfected quarterly. Must be documented on Quarterly Storage Area Clean in Pharmacy Keeper

3.7.4.4 See SOP 1.25 Cleaning Procedures for current agents in use.

3.7.5 In the event of a power outage lasting up to 3 hours, allow the PECs and the cleanroom to run for at least 30 minutes then clean and disinfect the entire PEC (and any equipment inside the PEC), work surfaces, and high touch areas before resuming compounding. Document per SOP 6.20 Variances.

3.7.6 In the event of a power outage lasting up to 72 hours, follow section 3.7.5 and additionally perform a monthly cleaning. Document monthly clean in Pharmacy Keeper

3.7.7 In the event of a power outage lasting more than 72 hours, follow sections 3.7.5 and 3.7.6 and additionally recertify the PECs and cleanroom.

3.7.8 Equipment and supplies must be wiped with sterile 70% IPA or another appropriate agent (while wearing gloves) immediately outside the anteroom or on the dirty side of the anteroom. Items must be wiped again with sterile 70% IPA before entering the ISO Class 5 PEC. Only equipment and supplies needed for compounding must enter the buffer room. Corrugated cardboard must not enter the buffer room and paper should be kept to a minimum.

3.8.5.1 Sterile syringes and similar items packaged in paper need to be wiped with 70% IPA.

3.9 Aseptic technique must be used at all times when working in the PEC. Use slow purposeful movements. Avoid coughing or sneezing over the work area. Minimize talking. Avoid leaning over the work area and resting hands on the work area. Do not allow head to enter the ISO Class 5 PEC. Ensure critical sites receive first air from HEPA filter. Do not allow hands, equipment or supplies to come between (shadow) critical sites and first air. Do not allow critical sites to touch hands or any nonsterile surface. Critical sites include but are not limited to needles; syringe tips, inner shafts and barrels; rubber stoppers on vials and IV bags; and open tops of vials and beakers.

4.0 References

4.1 Oklahoma Board of Pharmacy Laws and Rules

4.2 USP <797> Pharmaceutical Compounding – Sterile Preparations (2023)

5.0 Attachments

N/A

Version	Effective Date	Approved by	Description of Change
1	11-04-24	Jamie Russell	New SOP
2	01-06-25		Added Sections: 3.7.4.3, 3.7.5, 3.7.6, & 3.7.7

Verified by:	Title	Signature	Date
Jessica McMakin	Pharmacist in Charge		
Approved by:			
Jamie Russell	Designated Person		
Approved by:			
James Mangham	QA/QC Officer		

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for initial and ongoing training and competency at Pharmacorr Sterile

2.0 Definitions

2.1 N/A

3.0 Procedure

3.1 This procedure applies to all personnel involved with compounding activities.

3.2 **Orientation** for new employees must include:

3.2.1 Tour of Facility

3.2.2 Pharmacy Hours, Work Schedule, Lunch

3.2.3 Dress Code

3.2.4 Telephone Use

3.2.5 HIPAA, Pharmacy Security

3.2.6 Job Description

3.2.7 SOP Manual (includes OSHA Training)

3.2.8 Didactic Training (as applicable)

3.2.9 Equipment Training and Competency Assessment (as applicable)

3.2.10 Competency Assessment (as applicable)

3.3 SOP Manual must be read and Annual Review form located in the front of SOP manual must be signed initially by new employees and annually by all employees. Employees must read SOPs that are pertinent to their position.

3.4 Upon completion of orientation, **Orientation Checklist** (Attachment 2) along with resume. license verification, job description, **OSHA Training Checklist** (SOP 6.40 Attachment 10), and documentation of required training and competency assessments must be filed in employee training file.

3.4.1 Compounding personnel, pharmacists performing oversight of compounding personnel, pharmacist performing final verification of compounded preparations, and pharmacist-in-charge must complete orientation training and

competency assessments before performing regular job duties and at least annually thereafter (as required).

3.5 **Equipment training and competency assessment** must be performed before using equipment (or overseeing the use of equipment) and upon evidence of poor technique. Document on Equipment Training and Competency Assessment (Attachment 3).

3.6 **Competency Assessment**

3.6.1 **Sterile Compounding**

3.6.1.1 Sterile compounding personnel (including oversight personnel) must be trained and observed and interviewed for competency on sterile compounding and aseptic technique prior to performing sterile compounding independently. Competency must be continually evaluated and documented at least annually. Training and competency must include ensuring personnel understand the requirements in USP <797> as well as

3.6.1.1.1 Hand hygiene and garbing

3.6.1.1.2 Cleaning and sanitizing

3.6.1.1.3 Calculations, measuring, and mixing

3.6.1.1.4 Aseptic Technique

3.6.1.1.5 Achieving and/or maintaining sterility

3.6.1.1.6 Use of equipment

3.6.1.1.7 Documentation of the compounding process

3.6.1.1.8 Proper use of PECs and principles of HEPA-filtered unidirectional airflow within the ISO Class 5 area

3.6.1.1.9 Principles of movement of materials and personnel within the compoundin area

3.6.1.2 Compounding technique must be observed by a qualified person with media fills (and observed competency assessments that includes interviewing personnel) to assess sterile compounding skills prior to first performing sterile compounding (or overseeing sterile compounding) and repeated every three

months (Category 3 compounders), every six months (Category 2 compounders), and every twelve months (Oversight personnel who do not compound) and upon evidence of poor technique. Document on Competency Assessment Sterile Compounding (Attachment 5).

3.6.1.3 Sterile compounding personnel must perform media fill testing under conditions that closely simulate the most challenging or stressful conditions encountered. A post garb and post compounding gloved fingertip sample must be performed on each hand along with a post compounding surface sample of the direct compounding area. Incubate gloved fingertip and surface samples at 30° - 35°C for no less than 48 hours followed by 20° - 25°C for no less than 5 days. Post garb gloved fingertip samples must not exceed 0 cfu. Post media fill gloved fingertip samples and surface samples must not exceed 3 cfu. Incubate media fill at 30° - 35°C for 7 days followed by 20° - 25°C for 7 days. Note that sterile compounding personnel must pass three successive gloved fingertip samples on each hand with zero cfus prior to performing sterile compounding independently. Document on Attachment 5 or 5D.

3.6.1.3.1 Nonsterile-to-Sterile Media Fill Procedure

- Dissolve 3 g of nonsterile soybean-casein digest medium per 100ml of nonbacteriostatic water to make a 3% nonsterile solution
- Make 5 positive control
- Filter through a 0.2 or 0.22 micron filter into sterile containers

3.6.1.3.2 Sterile-to-Sterile Media Fill Procedure is performed by transferring sterile media into sterile containers

3.6.1.4 Sterile compounding personnel must be observed performing skills assessments related to (1) hand hygiene and garbing; (2) PEC cleaning and aseptic technique; (3) Cleaning and disinfecting procedures every six every three months (Category 3 compounders), every six months (Category 2 compounders), and every twelve months (Oversight personnel who do not compound) and upon evidence of poor technique. Document results on Sterile Compounding Skills Assessment - Hand

Hygiene and Garbing (Attachment 5A), Sterile Compounding Skills Assessment - PEC Cleaning and Aseptic Technique (Attachment 5B), and Sterile Compounding Skills Assessment - Cleaning and Disinfecting Procedures (Attachment 5C). Note that sterile compounding personnel must pass three hand hygiene and garbing competency assessments prior to performing sterile compounding independently.

3.6.1.5 Personnel who fail written testing, skills assessment or whose media fills show growth must undergo re-training and re-evaluation by qualified personnel prior to starting or resuming sterile compounding.

3.6.3 **Pharmacists must be trained and observed and interviewed for competency on checking compounded preparations** prior to performing checking, every twelve months thereafter and upon evidence of poor technique. Document on Pharmacist Check Training and Competency Assessment (Attachment 6).

3.6.4 **Pharmacists must be trained and observed and interviewed for competency on counseling of compounded preparations** prior to performing counseling, every twelve months thereafter and upon evidence of poor technique. Document on Pharmacist Counseling Training and Competency Assessment (Attachment 7)

3.7 **Didactic review**

3.7.1 Review of USP 797 and aseptic technique must be performed prior to performing or overseeing sterile compounding or checking compounded sterile preparations, at least every twelve months thereafter and upon evidence of poor technique. A written quiz must be completed to document understanding. File a copy of training and quiz in training file. Re-training required for scores < 80%.

3.8 Regular ongoing training related to compounding must be performed and may include live training, webinars, demonstrations, journal articles, drug information, calculations, mock recalls, etc. Training may be documented on Staff Training (Attachment 1), Staff Meeting Minutes (Attachment 9), NABP e-profile, Training Certificates, etc.

3.9 Equivalent forms or methods may be used to document training.

3.10 Training File Checklist (Attachment 8) may be used to track training.

3.11 Staff meetings must be held regularly and include issues related to quality, privacy or security, and compliance as well as staff training. Personnel in attendance must sign in for meeting and minutes must be documented on Attachment 9 or equivalent form.

4.0 References

4.1 Oklahoma Board of Pharmacy Laws and Rules

4.2 USP <797> Pharmaceutical Compounding – Sterile Preparations (2023)

5.0 Attachments

5.1 Attachment 1 Staff Training

5.2 Attachment 2 Orientation Checklist

5.3 Attachment 3 Equipment Training and Competency Assessment

5.5 Attachment 4 Competency Assessment Presterilization Procedures

5.6 Attachment 5 Competency Assessment Sterile Compounding

5.7 Attachment 6 Pharmacist Check Training/Competency Assessment

5.8 Attachment 7 Pharmacist Counseling Training/Competency Assessment

5.9 Attachment 8 Training File Checklist

Version	Effective Date	Approved by	Description of Change
1	11/4/24	Jamie Russell	New SOP
2	01/06/25	Jamie Russell	Changed Media fill forms/process
3	01/22/25	Jamie Russell	Changed attachment 5C
4	05/06/25	Jamie Russell	Updated Media fill Quantities

Verified by:	Title	Signature	Date
Jessica McMakin	Pharmacist in Charge		
Approved by:			
Jamie Russell	Designated Person		
Approved by:			
James Mangham	QA/QC Officer		

PHARMACORR STERILE

Staff Training

Required Training

Attach quiz ensuring it contains name, date, and grade. Retraining required for scores < 80%

Pharmacy Keeper:

Training	Date completed
HIPAA	
HITECH	
Anti-Kickback Statute	
Handwashing Procedures	
Donning/Doffing Training	
Introductions to Good Manufacturing Practice (CGMP)	
Introduction to USP 797	
Media Fill Training	
USP 795 Quiz	
USP 797 Quiz	
USP 800 Quiz	

In House Training:

Training	Date completed
Aseptic Technique Training	
Equipment Training (Quizzes logged on Equipment training log)	
Spill Cart & process for cleaning spills Training-(Spill Cart Competency Quiz)	
Receiving Packages Training	
OSHA Training in MP1	
COA Training Document and Quiz	

Written Quiz:

- USP 797 Quiz Date Completed: _____ Grade:_____

I have completed and understand the above training.

Print Name- _____

Signature- _____

Date-_____

Orientation Checklist

Employee_____ Hire Date _____

(Check all that apply)		**ALL EMPLOYEES**
___Pharmacist-in-charge		___Tour of Facility
___Compounding Pharmacist (S)		___Pharmacy Hours, Work Schedule, Lunch
___Compounding Technician (S)		___Dress Code
___Non-Compounding Technician		___Telephone Use
___Pharmacy Clerk		___Pharmacy Security
___Delivery Driver		___Resume and License Verification
___PCAB PI Coordinator		___Job Description
___ Designated Person		___SOP Manual (and OSHA Training Checklist)

Compounders, Checking Pharmacists and PIC must complete orientation training/competency before performing job duties. Attach all documentation listed (as applicable) and file in employee training file.

Initial Didactic Training (Review of USP 797 and Aseptic Technique with Quiz grade >80%)
Complete □ Not Applicable □

Initial Equipment Training/Competency (SOP 1.60 Att 3)
Complete □ Not Applicable □

Initial Process Training/Competency – Presterilization Procedures (SOP 1.60 Att 4)
Complete □ Not Applicable □

Initial Process Training/Competency - Pharmacist Check, Pharmacist Counseling (SOP 1.60 Att 6 & 7)
Complete □ Not Applicable □

Documentation of Sterile Training Program
Complete □ Not Applicable □

Initial Hand Hygiene and Garbing with Gloved Fingertip Sampling (3 times with zero cfu) (SOP 1.60 Att 5)
Complete □ Not Applicable □

Media Fills with Skills Assessment (SOP 1.60 Att 5)
Hand Hygiene and Garbing, PEC Cleaning and Aseptic Technique, Cleaning and Disinfecting Procedures
Complete □ Not Applicable □

I have completed the above orientation training and competency assessment. I understand the responsibilities of my position and feel competent to perform my job according to the pharmacy's SOPs.

Employee signature _____ Date _____

Pharmacist-in-charge signature _____ Date _____

Equipment Training and Competency Assessment

Employee _____ Title _____

Training

1) SOP read for procedure on operating, cleaning, calibrating and maintenance.

2) Demonstration of procedure on operating, cleaning, calibrating and maintenance performed by supervisor or experienced user.

Competency Assessment

Staff member was observed and interviewed by supervisor or experienced user operating, cleaning, calibrating and maintaining equipment per procedure. Comment on need for additional training or observation on back of form (use additional sheets as necessary).

Equipment	**Experience** Beginner Intermediate Advanced	**Training** Date SOP #	**Demonstration** Date Required for initial training.	**Competency** Date Observed by	**Employee** Date Sign to document competency and understanding	**Supervisor** Date Sign to document competency and understanding
Balance						
Crimper/Decapper						
Dishwasher						
Bubble Point Tester						
BSC Hood						
LAFW Hood						
Powder Hood						
Hot Plate						
Incubator						
Dry Heat Oven						
Refrigerator/Freezer						
Repeater Pump						
Autoclave						
Curis System						

Equipment Training and Competency Assessment

Employee _____ Title _____

Training

1) SOP read for procedure on operating, cleaning, calibrating and maintenance.

2) Demonstration of procedure on operating, cleaning, calibrating and maintenance performed by supervisor or experienced user.

Competency Assessment

Staff member was observed and interviewed by supervisor or experienced user operating, cleaning, calibrating and maintaining equipment per procedure. Comment on need for additional training or observation on back of form (use additional sheets as necessary).

Air Sampler						
Spill Cart						
Eyewash Station						

Competency Assessment
Sterile Compounding — Presterilization Procedures

Employee_____

Cleaning and Sanitizing

____ Cleans and disinfects PEC and work surfaces using appropriate agents
____ Knows dwell time for agents used
____ Cleans equipment and utensils after each use

Compounding

____ Balance is level with all feet touching work surface
____ Demonstrates how to calibrate the balance
____ Demonstrates proper use of the balance; weighs accurately
____ Selects proper devices for measuring liquids; measures accurately
____ Follows the MFR for proper mixing procedure
____ Does not permit excess supplies in the PEC
____ Does not expose any bare skin in the PEC
____ Ensures powders are wet or container before removing from PEC
____ Ensures beakers are covered before moving solutions to the buffer room
____ Returns components to their proper storage area
____ Performs QC accurately
____ Documents CR accurately

Comments:

Observed by _____ Date _____

Competency Assessment
Sterile Compounding

Nonsterile-to-Sterile Media Fill

Compounder_____ Observer _____

Start Date: Time: Temp: Humidity: Pressure:

End Time:

Soybean-Casein Digest Lot Number _____ Exp Date _____

SWFI (not bacteriostatic) Lot Number _____ Exp Date _____

Incubate media fill at 30° - 35°C for 7 d followed by 20° - 25°C for 7 d.
Document positive "+" or negative "-" on chart below. May stop if vial turns positive.

Day	Date	Control 1	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												

***15-150 ADDITIONAL MEDIA CONTROLS/TEST TRACKING ON ATTACHMENT 5.1**

Surface Media Lot/Exp _____ Pos/Neg Control _____

Surface Test Location _____ Results ____cfu Pass? Y N

Fingertip Media Lot/Exp _____ Pos/Neg Control _____

Fingertip Post Garb: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N

Fingertip Post Media: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N

Incubate surface and GFS samples at 30° - 35°C for no less than 48 h followed by 20° - 25°C for no less than 5 d.

Post garb GFS must = 0 cfu. Post media fill GFS and surface samples must not exceed 3 cfu.

Surface/Fingertip media results read on Date/Time _____

Media Fill Process: ☐ Pass ☐ Fail Confirmed by _____

Bubble Test Passing Reading _____ Actual Reading _____ Pass? Y N

Tape filter to form.

Competency Assessment
Sterile Compounding

Sterile-to-Sterile Media Fill

Attach description of Media Fill Procedure.

Compounder_____ Observer _____

Start Date: Time: Temp: Humidity:
End Time:

Soybean-Casein Digest Lot Number _____ Exp Date _____

Incubate media fill at 30° - 35°C for 7 d followed by 20° - 25°C for 7 d.
Document positive "+" or negative "-" on chart below. May stop if vial turns positive.

Day	Date										
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											

Surface Media Lot/Exp _____ Pos/Neg Control _____

Surface Test Location _____ Results ___cfu Pass? Y N

Fingertip Media Lot/Exp _____ Pos/Neg Control _____

Fingertip Post Garb: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N

Fingertip Post Media: R Hand Results ___cfu Pass? Y N L Hand Results ___cfu Pass? Y N

Incubate surface and GFS samples at 30° - 35°C for no less than 48 h followed by 20° - 25°C for no less than 5 d.

Post garb GFS must = 0 cfu. Post media fill GFS and surface samples must not exceed 3 cfu.

Surface/Fingertip media results read on Date/Time _____

Media Fill Process: ☐ Pass ☐ Fail Confirmed by _____

Sterile Compounding Skills Assessment
Hand Hygiene and Garbing

_____ Presents in a clean appropriate attire and manner

_____ Removes visible jewelry, ear buds, and headphones

_____ Wears no cosmetics or eyelash extenders; fingernails are clean, cut short and unpolished

_____ Brings no food, drinks, cell phones, or personal items into sterile compounding areas

_____ Is aware of the line of demarcation and dons shoe covers one at a time, placing the covered shoe on clean side of the line of demarcation as appropriate

_____ Dons head cover (and beard cover, if necessary) assuring that all hair is covered

_____ Dons sterile mask

_____ Performs hand hygiene by cleaning fingernails under running water then uses soap and water for at least 30 seconds to clean all surfaces of the fingers, hands, and wrists then cleans up to the elbows using a circular motion; Rinses hands holding them upright and allowing water to drip down to the elbows

_____ Dries hands then forearms using low-lint towel

_____ Does not touch faucet or sink during hand hygiene procedure

_____ Disinfects hands using an alcohol-based hand rub

_____ Dons sterile gloves in a manner to prevent contamination

_____ Dons coverall without letting any portion (except the bottom of the feet) touch the floor

_____ Wipes gloves with sterile 70% IPA then allows to dry

_____ Dons second set of sterile gloves

_____ Wipes gloves with sterile 70% IPA then allows to dry

_____ Routinely wipes gloves with sterile 70% IPA including prior to work in the direct compounding area and after touching items or surfaces that may contaminate gloves

_____ Removes and discards garb per facility policy

Comments:

The person assessed is immediately informed of all unacceptable activities and shown and informed of specific corrections.

Name_____ Evaluator _____ Date _____

Sterile Compounding Skills Assessment
PEC Cleaning and Aseptic Technique

_____ Ensures PEC runs at least 30 minutes (or as instructed by manufacturer) prior to use

_____ Prepares (or has knowledge of) correct concentration of cleaning and/or disinfectant solutions and labels with correct BUD; follows labeled dwell times

_____ Selects appropriate agents; uses sterile water, sterile one-step disinfectant cleaner, then sterile 70% IPA

_____ Cleans and disinfects LAFWs at least daily in the following order: screen covering HEPA filter, ceiling, IV bar, side walls, work surface (from cleanest to dirtiest – top down and back to front); cleans, and disinfects the BSC in the following order: screen covering HEPA filter, back, IV bar, side walls, work surface (from cleanest to dirtiest – top down and back to front)

_____ Cleans and disinfects after spills and splashes or when contamination is known or suspected

_____ Wipes the PEC with sterile 70% IPA before each batch preparation and every 30 minutes during continuous compounding unless the compounding process takes longer than 30 minutes then wipes at the end of the process

_____ Wipes equipment, supplies, components with sterile 70% IPA prior to placing in PEC; alternatively may open paper wrapped items at edge of PEC; ensures items are opened properly; introduces only essential items; arranges items properly; does not block air intake

_____ Does not interrupt, impede or divert flow of first-air to critical sites; avoids shadowing

_____ Does not contaminate PEC by coughing, sneezing, chewing gum or excessive talking

_____ Keeps head outside PEC; glass shield, if available, lowered to appropriate level

_____ Performs manipulations in the direct compounding area (DCA); understands the DCA starts 6" from front in horizontal flow PECs and is 4 inches above the work surface in vertical flow PECs; understands the air split in vertical flow PECs and avoids working in this area

_____ Does not expose critical sites to contact contamination or worse than ISO Class 5 air

_____ Wipes stoppers, injection ports, and ampule necks with sterile 70% IPA and allows to dry

_____ Uses correct procedures to affix needles to syringes and insert needles into vials; adds and removes air to balance pressure within vials when needed; avoids contact contamination and shadowing

_____ Allows drug to completely dissolve before removing contents

_____ Inspects CSPs for particulate matter and intact container-closure

_____ Routinely wipes sterile gloves with sterile 70% IPA

_____ Disposes of sharps and waste appropriately

Comments:

The person assessed is immediately informed of all unacceptable activities and shown and informed of specific corrections

Name_____ Evaluator _____ Date _____

Sterile Compounding Skills Assessment
Cleaning and Disinfecting Procedures

Daily Tasks:

_____ Follows hand hygiene and garbing procedures

_____ Prepares (or has knowledge of) correct concentration of cleaning and/or disinfectant solutions and labels with correct BUD

_____ Selects appropriate agents and supplies; follows labeled dwell times

_____ Cleans and disinfects PECs and equipment within PECs

_____ Cleans and disinfects work surfaces, pass-throughs, and high touch areas

_____ Cleans and disinfects sink

_____ Cleans and disinfects floors using designated mop, starts at wall opposite the entry door; mops floor surface in even strokes toward the operator; moves carts as needed to clean entire floor surface

_____ Mops buffer room first followed by anteroom

_____ Removes trash at the end of each shift

_____ Documents cleaning activities including agents used and dwell time

Monthly Tasks:

_____ Follows hand hygiene and garbing procedures

_____ Prepares (or has knowledge of) correct concentration of cleaning and/or disinfectant solutions and labels with correct BUD

_____ Selects appropriate agents (including an agent with sporicidal activity) and supplies; follows labeled dwell times

_____ Cleans and disinfects from cleanest to dirties; ceiling, walls, and storage shelving; buffer room first followed by anteroom; cleans and disinfects all surfaces

_____ Cleans and disinfects the exterior of PECs and other equipment and fixtures

_____ Cleans and disinfects storage shelves and the inside and outside of all totes

_____ Cleans and disinfects carts

_____ Cleans and disinfects chairs

_____ Cleans and disinfect the interior and exterior of trash bins

_____ Documents cleaning activities including agents used and dwell time

The person assessed is immediately informed of all unacceptable activities and shown and informed of specific corrections

Comments:

Name_____ Evaluator _____ Date ___

Gloved Fingertip Initial Assessment

Compounder_____

Incubate at 30° - 35°C for no less than 48 h followed by 20° - 25°C for no less than 5 d.
Results > 0 cfu fail. Keep this form retrievable.

30° - 35°C Incubation Start Date _____ Start Time _____

30°-35°C End Date	30°-35°C End Time	R Hand cfu	L Hand cfu	Read by	Pass/Fail
					☐ Pass ☐ Fail
					☐ Pass ☐ Fail
					☐ Pass ☐ Fail

20° - 25°C Incubation Start Date _____ Start Time _____

20°-25°C End Date	20°-25°C End Time	R Hand cfu	L Hand cfu	Read by	Pass/Fail
					☐ Pass ☐ Fail
					☐ Pass ☐ Fail
					☐ Pass ☐ Fail

Confirmed by _____ Signature _____

Pharmacist Check Training and Competency Assessment

Employee _____ Title _____

Employee experience level with process ☐ Beginner ☐ Intermediate ☐ Advanced

Initial - Employee has completed and has documentation of all didactic training related to the process including relevant SOPS? ☐ Yes ☐ No ☐ N/A

Initial - Demonstration of process by supervisor or experienced pharmacist checker performed?
☐ Yes ☐ No ☐ N/A by_____ Date_____

Observation of process by supervisor or experienced pharmacist checker performed

by_____ Date_____

Preparation/Strength/Dosage Form _____

Verified compounding record to original written order or refill information? ☐ Yes ☐ No ☐ N/A
Verified accuracy of original written order (on new prescriptions)? ☐ Yes ☐ No ☐ N/A
Verified accuracy of patient label including IACP and other auxiliary label? ☐ Yes ☐ No ☐ N/A
Verified as follows :

Formula accuracy including calculations?	☐ Yes ☐ No ☐ N/A
Compounding record complete and accurate?	☐ Yes ☐ No ☐ N/A
BUD?	☐ Yes ☐ No ☐ N/A
Quantity?	☐ Yes ☐ No ☐ N/A
Packaging and storage requirements?	☐ Yes ☐ No ☐ N/A
Capsule size and color ?	☐ Yes ☐ No ☐ N/A
Expected weight?	☐ Yes ☐ No ☐ N/A
(Including accuracy of preparations compounded by weight and dispensed by volume.)	
Color, odor, uniformity, integrity, viscosity?	☐ Yes ☐ No ☐ N/A
Clarity, no particles or leaks?	☐ Yes ☐ No ☐ N/A
pH?	☐ Yes ☐ No ☐ N/A
Sterility method and testing?	☐ Yes ☐ No ☐ N/A
Bubble test?	☐ Yes ☐ No ☐ N/A

Employee answers interview questions appropriately and verbalizes understanding of procedure?
☐ Yes ☐ No Comments:

Is additional training or observation needed? Y N

Observed by _____ Date _____

Additional Training/Observation:

By _____ Date _____

Pharmacist Counseling Training and Competency Assessment

Employee _____ Title _____

Employee experience level with process ☐ Beginner ☐ Intermediate ☐ Advanced

Initial - Employee has completed and has documentation of all didactic training related to the process including relevant SOPS? ☐ Yes ☐ No ☐ N/A

Initial - Demonstration of process by supervisor or experienced pharmacist checker performed by_____ Date_____

Observation of process by supervisor or experienced pharmacist checker performed

by_____ Date_____

Preparation/Strength/Dosage Form _____

Preparation name, strength, dosage form?	☐ Yes ☐ No ☐ N/A
Route of administration?	☐ Yes ☐ No ☐ N/A
Duration of therapy?	☐ Yes ☐ No ☐ N/A
Proper use?	☐ Yes ☐ No ☐ N/A
Proper storage?	☐ Yes ☐ No ☐ N/A
Proper handling?	☐ Yes ☐ No ☐ N/A
Proper disposal?	☐ Yes ☐ No ☐ N/A
Warnings and side effects?	☐ Yes ☐ No ☐ N/A
Signs of Deterioration?	☐ Yes ☐ No ☐ N/A
Action to be taken in the event of a missed dose?	☐ Yes ☐ No ☐ N/A
Refill information?	☐ Yes ☐ No ☐ N/A

Were the patient's questions answered adequately ☐ Yes ☐ No ☐ N/A

Employee answers interview questions appropriately and verbalizes understanding of procedure?
☐ Yes ☐ No

Comments:

Is additional training or observation needed? Y N

Observed by _____ Date _____

Additional Training/Observation:

By _____ Date _____

Training File Checklist
Non-Compounding Personnel

Annually

Yr _____

____ HIPAA Training
____ OSHA Training
____ SOPs Read

Yr _____

____ HIPAA Training
____ OSHA Training
____ SOPs Read

Yr _____

____ HIPAA Training
____ OSHA Training
____ SOPs Read

Training File Checklist
Sterile Compounders

Year _____

Every Three Months

Sterile Competency Assessment

____ ____ ____ ____ Media Fill

Annually

____ HIPAA Training
____ OSHA Training
____ SOPs Read
____ USP 797/Aseptic Training w/Quiz
____ Calculations

Potency Testing
____ Filtration
____ Steam
____ Dry Heat

Training File Checklist
Pharmacists

Year _____

Every Three Months
Sterile Competency Assessment
____ ____ ____ ____ Media Fill

Annually
____ HIPAA Training
____ OSHA Training
____ SOPs Read
____ USP 797/Aseptic Training w/Quiz
____ Calculations

Pharmacist Competency Assessment
____ Checking
____ Counseling

Potency Testing (if compounding)
____ Filtration
____ Steam
____ Dry Heat

Date: 7/02/25
In: 10:20 a
Out: ~~12:45~~ 13:45

☑ Periodic lq3
☐ New
☐ Closing
☐ Change of Ownership / Name / Location

RETAIL INSPECTION FORM

License No. 1-9721
OBNDD 10615963
DEA FP4867927
Licenses Current (Y) N

Business Hours:
Mon-Fri 8:00a-5:00p
Sat on Call Sun on Call

Oklahoma State Board of Pharmacy
2920 N Lincoln Blvd, Ste A, Oklahoma City, OK 73105
Phone (405) 521-3815 / Fax (405) 521-3758
www.pharmacy.ok.gov / pharmacy@pharmacy.ok.gov

PLEASE RETAIN UNTIL NEXT INSPECTION

Training Area (Y) N
Drug Supplier (Y) N
Sterile Compounding (Y) N
Balances W (Y) N
Hot/Cold Water (Y) N

NAME Pharmacorr Sterile PHONE 405-326-4782
ADDRESS 1500 SE 66th St. CITY OKC ZIP 73149

Employees at this location	OSBP #	License/Permit Displayed/Current Y	N	On Duty Y	N	Immunization Certificate Y	N	Preceptor Y	N
D.Ph.'s: (PIC) Jessica McMakin	14754	✓		✓		—		✓	
Carla Hawkins	12772	✓		✓		—		✓	

	OSBP #	License/Permit Displayed/Current Y	N	On Duty Y	N	Identification Y	N	Picture Y	N	Training Y	N
Interns:											
Techs: Alexus Arredando	21398	✓						✓		✓	
Jamie Russell	32015	✓		✓		✓		✓		✓	
James Mangham	18663	✓		✓		✓		✓		✓	
Alexus Mayfield-Bibby "Ana"	32863	✓						✓		✓	
Chanty Gardner	30797	✓						✓			

	Y	N		Y	N		Y	N
Non-DPh employees work before or after business hrs		✓	Non-DPh staff Identified on phone	—		8/2024 Diversion Prevention P&P	✓	
Open Vials in Fridge & Proper Expiration Date	—		DEA 222 forms executed or CSOS	—		3 Invoice files maintained	✓	
Refrigerator 46°F/°C Freezer: 8°F/°C Logs completed		✓	Lock Out Department		✓	CPR certification in-date	—	
Invoices for Drugs Transferred to Other Licensed Entities	—		CDS losses since last inspection		✓	3 Rx files maintained properly	✓	
CDS Refills: Originals ___ Nightly Log___ Logbook___	—		Mailing RX's outside of OK	✓		Outdated CDS destruction	—	
Outdated drugs removed from pharmacy within 6 months	—		Unit Dose Exp Dates Correct See Compd Forms			Last annual Inventory on file	✓	
Inadequate Staffing Reports for Review		✓	Outdated drugs in Active Stock		✓	Library Current	✓	
Counseling Offered on all New Prescriptions	✓		E-Kits at LTCF's (if yes, use form)		✓	Compounds (if yes, use form)	✓	

Comments: – No immunizations administered at this location.
– Multiple out of State licenses – No outdated drugs
* Currently no CDS special >6 months post. exp.
(1) Patient prescription label must have Storage requirements indicated or an attached auxiliary label to indicate product must be refrigerated
(2) Need OKBOPP tech exam on file for ± 30797 (Gardner) – will obtain
(3) All freezers containing API must have documented 2x daily temp or Cont. monitoring (Bulk API separate must be moved to breakroom 6/25).

Important: You are directed to take prompt action to correct the above violations. If such action is disregarded, Board action may result. These deficiencies have been explained and will be corrected.

Pharmacist: Compliance Officer:

2-93

Date: 7/02/25
In: 10:26 a.m.
Out: 13:45

Oklahoma State Board of Pharmacy
2920 N Lincoln Blvd, Ste A, Oklahoma City, OK 73105
Phone (405) 521-3815 / Fax (405) 521-3758
Website: www.pharmacy.ok.gov / E-mail: pharmacy@pharmacy.ok.gov

COMPOUNDING INSPECTION FORM

PLEASE RETAIN UNTIL NEXT INSPECTION

NAME Pharmacorr sterile LICENSE NO. 1-9721

ADDRESS 1500 SE 66th St. CITY OKC ZIP 73149

Compounding Categories (1-5), examples:

1) Magic Mouthwash, mixing two creams together
2) Capsules, tablets, suppositories, PLO gel, hormone therapy
3) Inhalant solution, IV antibiotics, 2 additives to IV solution, nmt 3 commercial products (low risk)
4) TPN's, multiple meds in IV (medium risk) Cat 2 segregated
5) Intrathecal, non-sterile powder used to prepare IV infusions (high risk), extended BUD

Pharmacy compounds: (check each that apply)

Category 1:___
Category 2:___
Category 3:___
Category 4:___
Category 5: ✓

All Compounding:	Y	N		Y	N		Y	N
Compounding area well-organized, sanitary	✓		Compounding observed by CO	✓		Outdated bulk chemicals		✓
Policies & Procedures Last updated 11/2024	✓		P&P Recall process combo	✓		Everything compounded onsite	✓	
Compounding commercial available products		✓	If yes, unavailability documented	—		Purified water source	✓	
Using USP or NF components	✓		If no, COA available	✓		MSDS files	✓	
Preparing veterinary products from bulk	—		Documentation of annual training	✓		Initial competency test on file	✓	
Proper CDS bulk documentation	—		Preparing "For Office Use" – pt specific		✓	"Office Use" properly labeled	—	

Non-Sterile Compounding:	Y	N		Y	N		Y	N
Compounding log/formula worksheets			DPh documenting verification			Actual weights documented		
Hazardous Drugs Stored Separately			Hazardous Drugs Cmpd in BSC			BSC Inspection Date_____		
Hazardous Cmpding Proper Garbing			Rx designated as compound			Label designated as cmpd		
BUD: From manufactured drug product: Non-aqueous/solid forms nmt 6 months or 25% of time remaining of mfg exp date			BUD: From USP/NF: non-aqueous/solid forms, nmt 6 months			BUD: Aqueous oral: nmt 14 days when refrigerated		
BUD: All other formulations: nmt 30 days			Equipment calibration log			Batch or lot # assigned		

Sterile Compounding:	Y	N		Y	N		Y	N
Anteroom: Class 8 Buffer Area: Class 7 Clean room: Class 7 LFH: Class 5 Barrier Isolator Class____ Chemo Hood: Class____								
Anteroom: Demarcation line or barrier	✓		Buffer Area: free of cardboard/lint	✓		Hood/Room Certificate date 12/2025	✓	
Surface areas impermeable, nonporous	✓		Cleaning supplies: Lint free ✓ Sporacidal ✓ Sterile IPA ✓ Industrial detergent ✓				✓	
Walls/Ceilings/Shelving monthly cleaning log	✓		Floors/Work Surfaces daily cleaning log	✓		Autoclave Cert Date_____	—	
Low Risk BUD: <48 hrs room temp, nmt 14 days refrigerated, nmt 45 days frozen	—		Med Risk BUD: <30 hrs rm temp, nmt 9 days refrigerated, nmt 45 days frozen	—		High Risk BUD: <24 hrs rm temp, nmt ~~14~~ 9 days ref, nmt 45 days frozen	✓	
Immediate-use cmpds begin admin w/in 1 hr 3 hr	✓		Temp and humidity monitored & logged	✓		Pressures Monitored and Logged	✓	
Aseptic testing technique: Annual & biannual	✓		Garb lint-free and sterile	✓		Garb worn properly	✓	
Separate hoods for cytotoxic products	—		Chemo hood vented to outdoors	—		Adequate quantities sampled 26	✓	
Sterility testing performed & documented	✓		Endotoxin testing performed	✓		Potency testing performed	✓	
Terminal sterilization: Autoclave or convection	—		Aseptic sterilization: Filter integrity test or COA	✓		Media fill &/or fingertip testing	✓	
Containers purchased presterilized	✓		If not, sterilization process documented	—		COA for sterile containers	✓	

Comments: DPh# 14754, DPh# 12772, T-32015, T-18663, T-27398, T-32363 perform sterile compounding/Designated Person.
- Pharmacy began compounding for dispensing 12/10/24
(1) Pharmacy's "Competency Assessment – Sterile Compounding" employee fingertip & Media Fill testing must have documented incubation temperature for the in-house testing for each employee
(2) Need to send sterility, endotoxin, potency send to OKBOP when results return for "Lot Compounded 07/01/25 (Lot# 07012025JAM)
Fridge #1 → 5.1°C Fridge #2 → 4.2°C

Important: You are directed to take prompt action to correct the above violations. If such action is disregarded, Board action may result. These deficiencies have been explained and will be corrected.

Pharmacist:	Compliance Officer:

6.4.2019

ADDITIONAL COMMENTS 3 of 3

NAME Pharmacor Sterile DATE 7/02/25

ADDRESS 1500 SE 66th St. LICENSE NO 1977

CITY OKC ZIP 73149

Additional Comments:

(3) Need to send Room/Hood certificates and Microbiology results when complete for upcoming 07/10/2025 visit.

[redacted]

(4) Need to send copy of method suitability for all 4 products currently compounding.

06/24/2025 – Ante Room Attention (temp.) → no actionable findings

- Pharmacy has studies available for shipment of sterile products – overnight shipment and same day delivery (temp.).
- Pharmacy currently looking into changing courier service.

Employee:	Compliance Officer:

OKLAHOMA

405-521-3815 • Fax 405-521-3758

State Board of Pharmacy
2920 N Lincoln Blvd Ste A, Oklahoma City, OK 73105

PHARMACY
#1-9721

RETAIL

EXPIRES JUL 31, 2026

PHARMACORR STERILE, LLC
1500 SE 66TH STREET
OKLAHOMA CITY, OK 73149

Permits
Training Area
Drug Supplier
Sterile Compound

2026

Amount: $255.00
Receipt: 14736259
Date: 7/7/2025

This License is not transferable.
License must be conspicuously displayed in the location to which it is issued.

Important Information

- **Change of Location:** This license is not transferable for a change of location. A new license is required.
- **Change of Name:** This license is not transferable for a change of name. A new license is required.
- **Change of Owner:** This license is not transferable for a change of owner. A new license is required when the ownership changes by 20% or more.
- **Forms & Applications, Current Announcements and Laws & Rules are available at the Board's website:** www.pharmacy.ok.gov
- **Board Contact:**

  Email: pharmacy@pharmacy.ok.gov

  Phone: 405-521-3815

  Fax: 405-900-8365

All changes in any information required for the licensure must be reported to the Board within ten (10) days.

It is your responsibility to keep this license current.

Oklahoma State Board of PHARMACY

Last Updated: 7/24/2025 5:23:37 AM

Pharmacy Detail

Back

Corporation / Company Owner Name	
Business (DBA) Name	PHARMACORR STERILE, LLC
License Number	1-9721
Type of Pharmacy	Retail
Address	1500 SE 66TH STREET
City, State, Zip	OKLAHOMA CITY, OK 73149
Country	
Issue Date	07/12/2024
Renewed Date	07/07/2025
Expiration Date	07/31/2026
End Date	
Replacing	
Replaced By	
Drug Supplier	Yes
Sterile Compounding	Yes
Training Area	Yes
Unused Drug Dispensing	No
LTC Emergency Kit	No
Pharmacist-In-Charge	JESSICA LEE MCMAKIN - 14754
Status	License in Good Standing
In Process?	

- **PRIMARY SOURCE VERIFICATION:** The Oklahoma State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website and considers the website to be a secure, primary source for license verification.
- **ATTENTION NEW REGISTRANTS!** Website verification is not an official certificate of registration. You cannot practice in Oklahoma until you have received a letter of registration, renewal or permit from the Board
- **WRITTEN VERIFICATION OF LICENSURE (OR LETTER OF GOOD STANDING):** There is a $10 fee for a certified verification of license from the Board. Website verification remains free.

Disciplinary Action

Click on any of the Underlined headings to sort by that column.

Case Date	Case Number
No Disciplinary Action	

OKLAHOMA
State Board of Pharmacy

2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105
Marty Hendrick, Pharm.D., D.Ph., Executive Director
pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov
Phone: 405.521.3815 • Fax: 405.521.3758

July 28, 2025

CERTIFIED LICENSE VERIFICATION

Name:	PHARMACORR STERILE, LLC
Address:	1500 SE 66TH STREET, OKLAHOMA CITY, OK 73149
License Number:	1-9721
Date Issued:	7/12/2024
Expiration Date:	7/31/2026
License Type:	RESIDENT PHARMACY
Disciplinary Action:	N/A
Licensure Status:	ACTIVE
Date of Last Inspection:	8/14/2024
Licensed By:	OKLAHOMA STATE BOARD OF PHARMACY
Verification Date:	July 28, 2025
Verified By:	Marquise Robertson *(MARQUISE ROBERTSON)*
Title:	ADMINISTRATIVE PROGRAM OFFICER II

SEAL

OKLAHOMA STATE BOARD OF PHARMACY

A Constitutional Board Established in 1907

President	Vice-President	Member	Member	Member	Member
Jim Spoon, D.Ph.	Justin Wilson, D.Ph.	Mark St. Cyr, D.Ph.	Jason Willeford	Greg Adams, D.Ph.	Kyle Whitehead, D.Ph.
Sand Springs	*Norman*	*Jones*	*Norman*	*Clinton*	

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP4807927	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-08-2024

PHARMACORR STERILE LLC
1500 SE 66TH ST
OKLAHOMA CITY, OK 73149

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distributa, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP4807927	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-08-2024

PHARMACORR STERILE LLC
1500 SE 66TH ST
OKLAHOMA CITY, OK 73149

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☒ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box) LLC
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PharmaLogic Los Angeles

Physical Address: 2250 Alcazar St

City: Los Angeles State: CA Zip: 90089

Mailing Address (if different from physical address): 2250 Alcazar St, Clinical Sciences Center, Room 101

City: Los Angeles State: CA Zip: 90089

Telephone: 213-647-4253 Toll Free # (NAC 639.708, NRS 639.23286): 877-217-8568

Fax: 213-814-1334 Contact Email: LosAngelesPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A; new license application

Supervising/Managing Pharmacist Name (NRS 639.220): An (Andy) Luong

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 15074

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: An (Andy) Luong	NV Pharmacist Registration #: 15074
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): PharmaLogic Holdings Corp

Corporation/Organization Name: PharmaLogic Los Angeles, LLC

Mailing Address: 2250 Alcazar St, Clinical Sciences Center, Room 101

City: Los Angeles State: CA Zip: 90089

Telephone: 213-647-4253 Email: LosAngelesPharmacy@radiopharmacy.com

Contact Person Name: An (Andy) Luong

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: PharmaLogic Holdings Corp

Business Name: PharmaLogic Holdings Corp

Business Address: 5301 N Federal Hwy, Suite 280

City: Boca Raton State: FL Zip: 33487

Telephone: 561-416-0085 Email: anthonymedel@radiopharmacy.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the VP Pharmacy Quality&Regulatory (title) for PharmaLogic Los Angeles, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jessica Comstock

Print Name of Authorized Person

Jessica Comstock

Original signature of Authorized Person (copies or stamps not accepted)

3/4/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Comstock

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Jessica Comstock

Original signature of Authorized Person (copies or stamps not accepted)

3/4/25

Date

Board Use Only	Date Received: 3/24/25	Amount: $500 - CK 100852

PharmaLogic
Take The Lead

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521
(775) 850-1440

October 5, 2025

Re: Change in Corporate Officer for PharmaLogic Los Angeles, LLC

To whom it may concern,

I am writing to formally notify the Nevada Board of Pharmacy of a recent change in the corporate officers within our organization, specifically pertaining to PharmaLogic Los Angeles, LLC (license application pending).

Corporate Officers:

- Etienne Montagut
- Mark Eugene Dmytruk
- Jessica Jean Comstock

Effective Date of Change: September 5, 2025

Should you require any additional information or documentation to process this change, please do not hesitate to contact me at 479-445-2010 or via email at phanby@radiopharmacy.com.

Thank you for your attention to this matter.

Kind regards,

Payton Hanby, PharmD, DipACLM
Pharmacy Regulatory Affairs Specialist
PharmaLogic Holding Corp
phanby@radiopharmacy.com
(479) 445-2010

Ownership



PharmaLogic Los Angeles Managing Officer

Steven Chilinski – President, Treasurer, and Secretary

[redacted]

No Medical Professional License
0% Ownership

Docusign Envelope ID: 8BF0D256-D84F-4EB7-BEE6-A51F9FD1F6C3

JOINT OMNIBUS WRITTEN CONSENT OF
THE GOVERNING BODIES
(as the case may be) of each of the following entities:

July 26, 2024

Blue Ridge Isotopes, LLC, a Virginia limited liability company
Clinical Pharmacy Services, Inc., a Tennessee corporation
CPI Pharmacy Services Holding, LLC, a Wisconsin limited liability company
Diagnostic Laboratories, LLC, a Tennessee limited liability company
Essential Isotopes, LLC, a Missouri limited liability company
Hot Shots NM, LLC, an Iowa limited liability company
Hot Shots Nuclear Medicine, LLC, a Wisconsin limited liability company
Invivo Molecular Imaging LLC, a Tennessee limited liability company
Isologic Innovative Radiopharmaceuticals Ltd., a Canadian corporation
Isotope Investments, LLC, a Delaware limited liability company
Mid-America Cyclotron, Inc., a Missouri corporation
Mid-America Isotopes, Inc., a Missouri corporation
Nuclear Diagnostics Products Inc., a New Jersey corporation
Nuclear Diagnostics Products of New York Inc., a New York corporation
Nuclear Diagnostics Products of Philadelphia Inc., a New Jersey corporation
PharmaLogic Austin, LLC, a Delaware limited liability company
PharmaLogic Cincinnati, LLC, a Delaware limited liability company
PharmaLogic Colorado, LLC, a Delaware limited liability company
PharmaLogic Georgia, LLC, a Delaware limited liability company
PharmaLogic Idaho, LLC, a Delaware limited liability company
PharmaLogic CSP, Inc., a Delaware corporation
PharmaLogic Holding Corp., a Delaware corporation
PharmaLogic Ltd., a Vermont corporation
PharmaLogic Los Angeles, LLC, a Delaware limited liability company
PharmaLogic ME, Inc., a Delaware corporation
PharmaLogic MI, L.L.C., a Michigan limited liability company
PharmaLogic MN, Inc., a Delaware corporation
PharmaLogic Molecular, LLC, a Delaware limited liability company
PharmaLogic MT, Inc., a Delaware corporation
PharmaLogic New York City, LLC, a Delaware limited liability company
PharmaLogic New York City RE, LLC, a Delaware limited liability company
PharmaLogic Penn Ltd., a Pennsylvania corporation
PharmaLogic Pittsburgh, LLC, a Delaware limited liability company
PharmaLogic Puerto Rico, Inc., a Puerto Rican corporation
PharmaLogic Salt Lake City, LLC, a Delaware limited liability company
PharmaLogic South Carolina, LLC, a Delaware limited liability company
PharmaLogic South Carolina RE, LLC, a Delaware limited liability company
PharmaLogic Syracuse, LLC, a New York limited liability company
PharmaLogic WV Ltd., a West Virginia corporation
PharmaLogic WY, Inc., a Delaware corporation
Precision Nuclear, LLC, a Tennessee limited liability company
Precision Nuclear of Virginia, LLC, a Virginia limited liability company
Radiopharmacy, Inc., an Indiana corporation
Radiopharmacy of Paducah, Inc., a Kentucky corporation
Rio Grande Valley Isotopes, L.L.C., a Texas limited liability company
UltraSPECT USA, LLC, a Delaware limited liability company
Wisconsin Medical Radiopharmacy, LLC., a Delaware limited liability company

The undersigned, being (i) the managing member, (ii) the manager(s), or (iii) all the members of the board of directors (the "**Governing Bodies**"), of the above-named companies (as applicable) (each, a "**Company**" and together, the "**Companies**"), hereby waive notice and consent, pursuant to the applicable statutes and the organizational documents of each such Company, to the adoption of, and do hereby adopt, the following resolutions and agree that said resolutions shall have the same effect as if duly adopted at a meeting of the governing body of such Company held for the purpose:

I. Appointment of Authorized Signatories

RESOLVED: That Jessica Comstock is hereby appointed as an authorized signatory of the Companies with respect to matters relating to the completion and submission of pharmacy, manufacturing and distribution licenses and no other matters, and that Jessica Comstock be, and hereby is, authorized and empowered from time to time to execute such pharmacy license-related documents and other instruments, in the name and on behalf of the Companies, as may be necessary or desirable in order to carry out the day-to-day pharmacy license-related operations of the Companies.

RESOLVED: That Ashley Mishoe is hereby appointed as an authorized signatory of the Companies with respect to matters relating to the completion and submission of regulatory filings and other instruments with the United States Food and Drug Administration ("**FDA**") and no other matters, and that Ashley Mishoe be, and hereby is, authorized and empowered from time to time to execute such FDA-related regulatory filings and other instruments, in the name and on behalf of the Companies, as may be necessary or desirable in order to carry out FDA-related regulatory filings and other instruments for the Companies.

II. General

RESOLVED: To authorize, empower and direct the Authorized Officers, as applicable, and each of them acting singly (i) to execute, and deliver in the name of and on behalf of the applicable Company any and all documents, agreements and instruments to effectuate any of the foregoing resolutions, all with such changes therein as any of such Authorized Officers may deem necessary or desirable, and (ii) to take such action (including without limitation the filing of any and all applications and the payment of any and all filing fees and expenses), or to cause the applicable Company or any other person to take such action as may in the judgment of such Authorized Officer so acting be necessary or desirable in connection with, or in furtherance of, any of the foregoing resolutions, and the execution and delivery of any such document, agreement or instrument or the taking of any such action shall be conclusive evidence of such Authorized Officer's authority hereunder to so act.

RESOLVED: To ratify, confirm and approve all actions taken by the directors, managers, members and/or the officers of each Company, as applicable, in connection with the any and all of the transactions referred to in or contemplated by any of the foregoing resolutions.

RESOLVED: A signed PDF, JPG, facsimile or other electronic image of this document shall be given the same legal effect as an executed original.

RESOLVED: That this Joint Omnibus Written Consent of the Governing Bodies may be signed in multiple counterparts, including by facsimile or other electronic transmission, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same instrument.

RESOLVED: The undersigned further directs that this written consent shall be filed with the corporate records of the applicable Company.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth above.

PHARMALOGIC HOLDINGS CORP., as Manager of:

Blue Ridge Isotopes, LLC, a Virginia limited liability company
Diagnostic Laboratories, LLC, a Tennessee limited liability company
Hot Shots Nuclear Medicine, LLC, a Wisconsin limited liability company
Invivo Molecular Imaging LLC, a Tennessee limited liability company
Isotope Investments, LLC, a Delaware limited liability company
PharmaLogic Austin, LLC, a Delaware limited liability company
PharmaLogic Cincinnati, LLC, a Delaware limited liability company
PharmaLogic Colorado, LLC, a Delaware limited liability company
PharmaLogic Georgia, LLC, a Delaware limited liability company
PharmaLogic Idaho, LLC, a Delaware limited liability company
PharmaLogic MI, L.L.C., a Michigan limited liability company
PharmaLogic Molecular, LLC, a Delaware corporation
PharmaLogic New York City, LLC, a Delaware limited liability company
PharmaLogic New York City RE, LLC, a Delaware limited liability company
PharmaLogic Pittsburgh, LLC, a Delaware limited liability company
PharmaLogic Salt Lake City, LLC, a Delaware limited liability company
PharmaLogic South Carolina, LLC, a Delaware limited liability company
PharmaLogic South Carolina RE, LLC, a Delaware limited liability company
PharmaLogic Syracuse, LLC, a New York limited liability company
Precision Nuclear of Virginia, LLC, a Virginia limited liability company
Precision Nuclear, LLC, a Tennessee limited liability company
Rio Grande Valley Isotopes, L.L.C., a Texas limited liability company
UltraSPECT USA, LLC, a Delaware limited liability company
Wisconsin Medical Radiopharmacy, LLC., a Delaware limited liability company

DocuSigned by:
By: Steven Chilinski
233B0FCBDD1F4F8...
Steven Chilinski
President

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth above.

MANAGING MEMBER of:

HOT SHOTS NUCLEAR MEDICINE, LLC, as Managing Member of:

Hot Shots NM, LLC, an Iowa limited liability company
CPI Pharmacy Services Holding, LLC, a Wisconsin limited liability company

By: PHARMALOGIC HOLDINGS, CORP.,
its Manager

DocuSigned by:
By: Steven Chilinski
233B8FCBDD1F4F8...
Steven Chilinski
President

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth above.

MANAGING MEMBER of:

MID-AMERICA CYCLOTRON, INC., as Managing Member of:

Essential Isotopes, LLC, a Missouri limited liability company

DocuSigned by:

By: Steven Chilinski
233B8FCBDD1F4F8...

Steven Chilinski, CEO

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of:

Clinical Pharmacy Services, Inc., a Tennessee corporation
Mid-America Cyclotron, Inc., a Missouri corporation
Mid-America Isotopes, Inc., a Missouri corporation
Nuclear Diagnostics Products Inc., a New Jersey corporation
Nuclear Diagnostics Products of New York Inc., a New York corporation
Nuclear Diagnostics Products of Philadelphia Inc., a New Jersey corporation
PharmaLogic CSP, Inc., a Delaware corporation
PharmaLogic Holdings Corp., a Delaware corporation
PharmaLogic Ltd., a Vermont corporation
PharmaLogic ME, Inc., a Delaware corporation
PharmaLogic MN, Inc., a Delaware corporation
PharmaLogic MT, Inc., a Delaware corporation
PharmaLogic Penn Ltd., a Pennsylvania corporation
PharmaLogic Puerto Rico, Inc., a Puerto Rican corporation
PharmaLogic WV Ltd., a West Virginia corporation
PharmaLogic WY, Inc., a Delaware corporation
Radiopharmacy of Paducah, Inc., a Kentucky corporation

DocuSigned by:
Steven Chilinski
233B8FCBDD1F4F8...
Steven Chilinski

Signed by:
John Garbarino
5ACF8644D43E4B4...
John Garbarino

DocuSigned by:
Brandon Ingersoll
C88684B54BF044D...
Brandon Ingersoll

DocuSigned by:
David Malm
A862C874DF824B5...
David Malm

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of:

Radiopharmacy, Inc., an Indiana corporation

DocuSigned by:
Steven Chilinski
233B8FCBDD1F4F8...
Steven Chilinski

DocuSigned by:
David Malm
A082C874DF824B5...
David Malm

DocuSigned by:
Brandon Ingersoll
C98664B54BF844D...
Brandon Ingersoll

IN WITNESS WHEREOF, the undersigned have duly executed this written consent as of the date first set forth below.

BOARD OF DIRECTORS of:

Isologic Innovative Radiopharmaceuticals Ltd., a Canadian corporation

DocuSigned by:
153E7B5D64C74C3...
Andre Gagnon

DocuSigned by:
A062C874DF824B5...
David Malm

DocuSigned by:
C98684B54BF044D...
Brandon Ingersoll

Signed by:
5AGF8644D43E4B4...
John Garbarino

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHARMALOGIC LOS ANGELES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF SEPTEMBER, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHARMALOGIC LOS ANGELES, LLC" WAS FORMED ON THE TWENTY-FOURTH DAY OF NOVEMBER, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6424279 8300

SR# 20253728635

Authentication: 204700602

Date: 09-09-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PharmaLogic Los Angeles, LLC dba PharmaLogic Los Angeles

Pharmacy/Wholesaler License # (if applicable) N/A; new license application

Physical Address 2250 Alcazar St

City Los Angeles State CA Zip 90089

Mailing Address (if different from physical address) 2250 Alcazar Street, Clinical Sciences Center Room 101

City Los Angeles State CA Zip 90033

Telephone 213-647-4253 Website www.radiopharmacy.com

Licensing Company Email LosAngelesPharmacy@radiopharmacy.com

Section 2: Personal Information

First An Middle Khanh Last Luong

Alias(es, nicknames, name changes, etc.) Andy

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Midwestern University Chicago College of Pharmacy			08/95 - 05/99	
Address		City	State	Zip
555 31st Street		Downers Grove	CA	60515
Diploma/Degree obtained, if any				
Pharm.D.				
School Name			From - To (MM/YY – MM/YY)	
University of California, Davis			09/91 - 06/93	
Address		City	State	Zip
1 Shields Ave		Davis	CA	95616
Diploma/Degree obtained, if any				
B.S. Biochemistry				
School Name			From - To (MM/YY – MM/YY)	
Huntington Beach High School			09/84-06/88	
Address		City	State	Zip
1905 Main Street		Huntington Beach	CA	92648
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
01/10 - Present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
PharmaLogic Los Angeles, LLC dba PharmaLogic Los Angeles			04/23 - Present
Business Address	**City**	**State**	**Zip**
2250 Alcaraz St	Los Angeles	CA	90089
Phone	**Title**	**Number of Employed Hours**	
213-647-4253	Pharmacy Manager	3500	

Description of Duties

Ensure staff practices are in compliance with BOP. Customer data gathering for onboarding. Site setup, furniture,equipment, materials acquisition. USP 825 compliance. Radiation Safety. Dispensing sterile injectables.

Business Name			From - To (MM/YY – MM/YY)
PETNet Solutions			01/16 - 04/23
Business Address	**City**	**State**	**Zip**
6140 Bristol Pkwy	Culver City	CA	90230
Phone	**Title**	**Number of Employed Hours**	
310-670-1010	Pharmacist in Charge	13500	

Description of Duties

Ensure staff practices are in compliance with BOP and FDA regulations as outlined in company SOPs., dispensing PET injectables, investigations, operator qualifications in aseptic techniques, environmental monitoring, delivery logistics, etc.

Business Name			From - To (MM/YY – MM/YY)
PETNet Solutions			01/15-01/16
Business Address	**City**	**State**	**Zip**
11234 Anderson St	Loma Linda	CA	92354
Phone	**Title**	**Number of Employed Hours**	
909-799-0725	Pharmacy Manager	1000	

Description of Duties

New site opening, host inspections by FDA, CA Food and Drug Branch, CA Rad Health Branch, BOP. Hire and train staff to prepare for Grand Opening: cyclotron engineer, production tech, pharmacy tech, and staff pharmacists.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, An Luong, **certify that as the designated representative for**

PharmaLogic Los Angeles, LLC dba PharmaLogic Los Angeles,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AL I am at least 21 years of age;
3. AL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

An Luong

Print Name (First, Last)

An Luong

Original Signature (electronic, copies or stamps not accepted)

02-25-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

An Luong

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02-25-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Calgorma, ss. County of Orange

I, An Luong, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02-25-2025

Date

Subscribed and Sworn to before me this 25th day of Feb., 2025.

Notary Public Signature

UMANG G. DARANIYA
COMM. #2348155
NOTARY PUBLIC - CALIFORNIA
ORANGE COUNTY
My Comm. Expires March 16, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: PharmaLogic Los Angeles

NV Pharmacy or Outsourcing facility license # (if applicable): pending; new license application

Physical Address: 2250 Alcazar St, Clinical Sciences Center Room 101

City: Los Angeles State: CA Zip: 90089

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 213-647-4253 Toll Free # (NAC 639.708, NRS 639.23286): 877-217-8568

Fax: 213-814-1334 Contact Email: LosAngelesPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A; new license application

Supervising/Managing Pharmacist Name (NRS 639.220): An (Andy) Luong

Supervising/Managing Pharmacist NV Pharmacist Registration #: 15074

Name of Designated Person(s) as defined by revised USP-797 guidelines: An (Andy) Luong

Email of Designated Person(s): aluong@radiopharmacy.com

Telephone of Designated Person(s): 213-647-4253

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ☐ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 11/15/2024

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? At least monthly internally; completed every 6 months by an external vendor

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

F-18 Pylarify

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?

All products are inspected before and after preparation for any visible particles, abnormal coloration, and/or turbidity. If the product does not pass visual inspection, the product is quarantined and the compounding pharmacist will reach out to the Quality and Regulatory Department for next steps/to initiate investigations as needed.

14. How often do you perform glove fingertip and medial fill testing?

In triplicate as part of the onboarding process, then annually thereafter.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Please see SOP 6.02 - Aseptic Qualifications, 6.03 - Gowning, Garbing, and Hand Hygiene, and 7.05 - Network Training for our initial and annual training program for all personnel performing sterile compounding.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see SOP 6.04 - Cleaning of Clean Rooms and SRPAs and 6.05 - Cleaning of Clean LFHs and BSCs for the cleaning of our primary and secondary engineering controls, including frequency and names of approved agents used as cleaners/disinfectants and sporicidals.

17. Who performs the sterile compounding process at your facility?

Authorized nuclear pharmacists (ANPs) perform the sterile compounding process at PharmaLogic Los Angeles.

18. Who is responsible and accountable for the sterile compounding process at your facility?

An (Andy) Luong, Pharmacist-in-Charge

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All products that are delivered/shipped follow DoT regulations and emergency procedures for handling radioactive materials. The delivery process is either initiated after quality control tests are completed, or delivered under quarantine and only released to the customer upon the successful completion of quality control tests.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device: N/A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

N/A

5. What is the frequency for completing surface sampling? N/A		
6. What is the frequency for using sporicidal agents? N/A		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Payton Hanby

Name of Person who Completed the Form

Pharmacy Regulatory Affairs Specialist

Title

Signature (copies or stamps not accepted)

03/14/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy __X__ Hospital Pharmacy ____ Clinic ____ Exempt Hospital ____ Wholesaler ____ Hypodermic ____

Date: 10/10/2024 Inspector: Suzy Patell

Firm: PHARMALOGIC LOS ANGELES Phone: (213) 647-4253

Address: 2250 Alcazar St CSC-B7C City: Los Angeles Zip: 90089

Ownership: LLC

Permit #: LSC000000 PHY00000 Permit Exp: DEA#: DEA Exp:

Date of Self Assessment Form: 8/3/2023 Other Permit #: N/A Date of DEA Inventory: ____

Hours M-F: 0600-1400 Hours Saturday closed Hours Sunday: closed

PIC AN K LUONG RPH50805 Administrator ____

RPH Consultant ____

Staff RPH Name:	License #:	Staff Name:	License #:
SAVANNA R SCHULTZ	RPH88463		

Inspector Remarks:

Closed door nuclear pharmacy seeking licensure. Inspection conducted with PIC An 'Andy' Khanh Luong and RPH Savanna Schultz. Location is in basement of CSC building in Suite B7.

*Suite B7 is licensed by CDPH (Lic#121147; Exp:10/24/2025) as a drug manufacturer. Manufacturing is currently limited to Pylarify (F18 base; t1/2 of 110 min) a PET drug for prostate imaging, with future plans for IND drugs. Per PIC, no non-radio CSPs compounded.

*Manufacturing uses the following rooms: Rm B7A (control room with sink, access to anteroom and QA room); Rm B7B (QA room with gas chromatography stations); Rm B7C (anteroom); Rm B7D (buffer room with one BSC and one hot cell dedicated for manufacturing); Rm B7E (storage for manufacturing); Rm B7F (Chemistry lab for manufacturing); Rm B7G (storage for manufacturing); Rm B7H (an alcove of B7J for manufacturing); Rm B7I not a separate room- absorbed into B7J; Rm B7J (cyclotron vault for manufacturing).

*Pharmacy has applied for licensure of Suite B7 as a pharmacy and as a sterile compounding location. They plan to dispense dose draws of Pylarify and reconstituted kits like Netspot and Illuccix with Ga68 (half life of 68 minutes). Per PIC, anticipated daily volume is 1-3 doses per day, building up to 50 doses per day once pharmacy is open. Pharmacy plans to use Rm B7A (control room with sink, access to anteroom and QA room); Rm B7B (QA room with gas chromatography stations to be used by manufacturing, but a portion of counter space to be used by pharmacy for thin layer chromatography for Gallium products made from kits); Rm B7C (anteroom); Rm B7D (buffer room with one BSC and one hot cell dedicated for pharmacy)

* Per PIC, keys to Suite B7 are in RPH possession only and RPH is present when manufacturing operations are conducted; manufacturing (Pylarify) and compounding Gallium) could potentially occur at the same time.

Documents reviewed: 10/10/2024

NEW LSC INSPECTION:

Compounding Area: Sink with hot/cold water located in Rm A, just outside of anteroom (Rm C). Anteroom is an ISO 8 positive pressure room with clean/dirty sides, storage cabinet, garbing bench, garbing rack/bins, mirror leading to an ISO 7 positive pressure buffer room with a small ISO 5 BSC and an ISO 5 hot cell 1- both used by manufacturing; an ISO 5 BSC and an ISO 5 hot cell 2-both for pharmacy use; metal tables, pass through window to the QA room.

Certification/Smoke pattern video: via ENV Services 5/16 and 5/17/2024. Videos viewed onsite.

Environmental viable sampling: viable volumetric air and surface sampling- bacterial and fungal- in all ISO areas; surface

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

sampling inside pass through window via ENV Services 5/16-5/17/2024. Surface sampling conducted weekly, in-house, for August and September 2024 reviewed w/PIC and cfu identification, trending discussed.
Record Keeping Requirements:

- Master Formulation Record: Netspot (68 Ga Dotatate) and Illuccix (68 Ga Gozetotide) available.
- Label: date compounded; 'compounded by' notification; storage: available
- Cleaning Documentation: Currently cleaning on the days manufacturing occurs
- Refrigerator/Room/Incubator Temp., Pressure: logs available. Incubator min-max, reset procedures and documentation best practices when pharmacy is closed discussed w/PIC and RPH Schultz
- Training: gloved fingertip sampling (post garbing and post media fill); observational validation of daily, monthly cleaning, hand hygiene and garbing, aseptic technique; media fill validation for hot cell and BSC (with post validation DCA surface sampling); written/math available for PIC. Gravimetric air sampling during media fill validation noted.

Protective Clothing: available in competency assessment documentation
Policy and Procedures: .

- Designated person(s) listed in SOPs: PIC An Khanh Luong is DP
- Hand hygiene and garbing: reviewed with PIC based on location of sink outside anteroom.

Education, Discussion: New USP 797, 825, upcoming regulations in Board website pointed out.
Please note the board may be in further communication with the facility post inspection.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) AN KHANH LUONG

Inspector (sign) _____

Inspector (print) SUZY PATEL

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 10/10/2024 Permit #: LSC000000

Time of Day: 12:00 AM

Name as shown on permit: **PHARMALOGIC LOS ANGELES**

Address: 2250 Alcazar St CSC-B7C City: Los Angeles

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **A-None** A-None

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) Suzy Patel Signed An Khanh Luong

Inspector (print) Suzy Patel Print Name An Khanh Luong

Date 10/10/2024 Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

dca SEARCH

BOARD OF PHARMACY

ISSUANCE DATE
OCTOBER 18, 2024
EXPIRATION DATE
APRIL 15, 2025
CURRENT DATE / TIME
MARCH 14, 2025
12:30:52 PM

LICENSING DETAILS FOR: PHY 59225

NAME: PHARMALOGIC LOS ANGELES

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

2250 ALCAZAR ST
LOS ANGELES CA 90089
LOS ANGELES COUNTY

LICENSE RELATIONSHIPS

NAME: PHARMALOGIC LOS ANGELES

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101875 **PRIMARY STATUS:** CLEAR

ADDRESS :
2250 ALCAZAR ST
B7A-D
LOS ANGELES CA 90089
LOS ANGELES COUNTY

NAME: LUONG, AN KHANH

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 50805 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

dca SEARCH

BOARD OF PHARMACY

ISSUANCE DATE
OCTOBER 18, 2024
EXPIRATION DATE
APRIL 15, 2025
CURRENT DATE / TIME
MARCH 14, 2025
12:29:9 PM

LICENSING DETAILS FOR: LSC 101875

NAME: PHARMALOGIC LOS ANGELES

LICENSE TYPE: STERILE COMPOUNDING PHARMACY

LICENSE STATUS: CLEAR

ADDRESS

2250 ALCAZAR ST
B7A-D
LOS ANGELES CA 90089
LOS ANGELES COUNTY

LICENSE RELATIONSHIPS

NAME: PHARMALOGIC LOS ANGELES

LICENSE/REGISTRATION TYPE: PHARMACY (COMMUNITY)

LICENSE NUMBER: 59225 **PRIMARY STATUS:** CLEAR

ADDRESS :
2250 ALCAZAR ST
LOS ANGELES CA 90089
LOS ANGELES COUNTY

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: FC4852237 ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Cubance LLC dba Source Pharmacy

Physical Address: 8170 Okeechobee Blvd, Suite 4

City: West Palm Beach State: FL Zip: 33411

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855-437-7316 Toll Free # (NAC 639.708, NRS 639.23286): (855) 437-7316

Fax: (561) 666-4018 Contact Email: licensing@sourcerxpharmacy.com

Website: sourcerx.health

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Gregory Allen Brown

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Gregory Allen Brown	NV Pharmacist Registration #: 24860
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): N/A

Corporation/Organization Name: Cubance, LLC

Mailing Address: 8170 Okeechobee Blvd, Suite 4

City: West Palm Beach State: Florida Zip: 33411

Telephone: 855-437-7316 Email: licensing@sourcerxpharmacy.com

Contact Person Name: Franck Kacou

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Cubance LLC dba Source Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Franck Kacou

Print Name of Authorized Person

Frank K

Original signature of Authorized Person (copies or stamps not accepted)

11/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Franck Kacou

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/11/25
Date

Board Use Only	Date Received: 11/24/25	Amount: $500 CK 00106

Source Pharmacy

ORGANIZATIONAL CHART

Cubance, LLC DBA Source Pharmacy

Name: Franck Kacou

Title: President

Home Address: [redacted]

Work Address: 8170 Okeechobee Blvd Suite 4, West Palm Beach Florida 33411

[redacted]

Percentage of Ownership: 50%

Name: Leonard Pastrana

Title: Vice President

Home Address: [redacted]

Work Address: 8170 Okeechobee Blvd Suite 4, West Palm Beach Florida 33411

[redacted]

Percentage of Ownership: 50%

State of Florida
Department of State

I certify from the records of this office that CUBANCE, LLC is a limited liability company organized under the laws of the State of Florida, filed on May 19, 2022.

The document number of this limited liability company is L22000234376.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on January 28, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-fifth day of November, 2025

Secretary of State

Tracking Number: 9069565910CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC4852237	08-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,4,5	RETAIL PHARMACY	10-24-2024

CUBANCE LLC
SOURCE RX
8170 OKEECHOBEE BLVD STE 4
WEST PALM BEACH, FL 33411

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC4852237	08-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,4,5	RETAIL PHARMACY	10-24-2024

CUBANCE LLC
SOURCE RX
8170 OKEECHOBEE BLVD STE 4
WEST PALM BEACH, FL 33411

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Cubance LLC dba Source Pharmacy

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 8170 Okeechobee Blvd, Suite 4

City: West Palm Beach State: FL Zip: 33411

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-437-7316 Website: https://sourcerx.health/

Licensing Company Email: licensing@sourcerxpharmacy.com

Section 2: Personal Information

First: Gregory Middle: Allen Last: Brown

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: FL Zip: 33478

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL - PHARMACY			08/94 - 05/97	
Address	City	State	Zip	
301 PHARMACY LANE	CHAPEL HILL	NC	27599	
Diploma/Degree obtained, if any				
BS PHARMACY				

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL - UNDERGRAD			1/91 - 05/94	
Address	City	State	Zip	
UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL	CHAPEL HILL	NC	27514	
Diploma/Degree obtained, if any				
UNDERGRAD COURSES FOR PHARMACY SCHOOL				

School Name			From - To (MM/YY – MM/YY)	
EAST WAKE HIGH SCHOOL			08/86 - 05/90	
Address	City	State	Zip	
5101 ROLESVILLE RD	WENDELL	NC	27591	
Diploma/Degree obtained, if any				
GRADUATE				

School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/18 - CURRENT	[redacted]			
07/05 - 02/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: PROGRESS PHARMACY			From - To (MM/YY – MM/YY): 09/18 - CURRENT
Business Address: 8170 OKEECHOBEE BLVD #5	City: WEST PALM BEACH	State: FL	Zip: 33411
Phone: 561-720-2676	Title: PHARMACIST		Number of Employed Hours: 34/ WEEK
Description of Duties: TYPICAL INDEPENDENT RETAIL PHARMACIST DUTIES... INTAKING RX'S FINAL VERIFICATION OF RXS, INVENTORY CONTROL, OVERSEEING COMPOUNDING DEPT			
Business Name: TRUSTBRIDGE PHARMACY (HOSPICE OF PALM BEACH COUNTY)			From - To (MM/YY – MM/YY): 08/18 - CURRENT
Business Address: 300 NORTHPOINT PKWY SUITE 301	City: WEST PALM BEACH	State: FL	Zip: 33407
Phone: 561-242-2500	Title: PHARMACIST		Number of Employed Hours: 40/WEEK
Description of Duties: NORMAL PHARMACIST DUTIES - INITIAL + FINAL VERIFICATION OF RXS, ANSWER CLINICAL PALLIATIVE CARE DRUG QUESTIONS FOR OUR MD's + RN's - ONCALL ONCE EVERY 7 WEEKS			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Gregory Allen Brown, **certify that as the designated representative for**

Cubance LLC dba Source Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gregory Allen Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gregory Allen Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/25

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of Palm Beach

I, GREGORY ALLEN BROWN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/11/25

Date

Subscribed and Sworn to before me this 11th day of November.

Notary Public Signature

Notary Public State of Florida
Jessica Duarte
My Commission HH 526212
Expires 5/12/2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Cubance LLC dba Source Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 8170 Okeechobee Blvd, Suite 4

City West Palm Beach State FL Zip 33411

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-437-7316 Website sourcerx.health

Licensing Company Email licensing@sourcerxpharmacy.com

Section 2: Personal Information

First Leonard Middle _____ Last Pastrana

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephon[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Palm Beach Atlantic University			8/2004 - 8/2009	
Address		City	State	Zip
901 S. Flagler Dr		West Palm Beach	Fl	33401
Diploma/Degree obtained, if any				
Pharm D.				

School Name			From - To (MM/YY – MM/YY)	
Florida State University			08/99 - 8/03	
Address		City	State	Zip
222 S. Copeland Street		Tallahassee	Fl	32306
Diploma/Degree obtained, if any				
A.A degree				

School Name			From - To (MM/YY – MM/YY)	
Wellington Highschool			8/95 - 8/99	
Address		City	State	Zip
2101 Greenview Shores		Wellington	Fl	33414
Diploma/Degree obtained, if any				
Highschool diploma				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
3/25 - current	[redacted]			
6/15 - 3/25				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
NvBioAge			8/20 – current	
Business Address	**City**	**State**	**Zip**	
9140 Okeechobee blvd	West Palm Beach	FL	33411	
Phone	**Title**			
561-603-0409	Founder			
Description of Duties				
medical educations, webinars, Clinical Briefs				

Business Name			From - To (MM/YY – MM/YY)	
Rx Robinhood				
Business Address	**City**	**State**	**Zip**	
13860 Wellington trace 33-126	Wellington	FL	33414	
Phone	**Title**			
561-603-0409	Owner			
Description of Duties				
Provide consulting services for pharmacies and business owners.				

Business Name			From - To (MM/YY – MM/YY)	
Wood Samaritan Hospital			8/16 – 9/19	
Business Address	**City**	**State**	**Zip**	
1309 N. Flagler Dr.	West Palm Beach	FL	33401	
Phone	**Title**			
561-655-5511				
Description of Duties				
Clinical Pharmacist.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leonard Pastrana

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/25

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of Palm Beach

I, Leonard PeStrana, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/11/25

Date

Subscribed and Sworn to before me this 11th day of November.

Notary Public Signature

Notary Public State of Florida
Jessica Duarte
My Commission HH 526212
Expires 5/12/2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Cubance LLC dba Source Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 8170 Okeechobee Blvd, Suite 4

City: West Palm Beach State: FL Zip: 33411

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 855-437-7316 Website: sourcerx.health

Licensing Company Email: licensing@sourcerxpharmacy.com

Section 2: Personal Information

First: Franck Middle: Last: Kacou

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
the UNIVERSITY of FLORIDA	10/10 - 12/12		
Address	City	State	Zip
	GAINESVILLE	FL	32611
Diploma/Degree obtained, if any			
MASTER BUSINESS ADMINISTRATION			

School Name	From - To (MM/YY – MM/YY)		
PALM BEACH ATLANTIC UNIVERSITY	08/03 - 05/07		
Address	City	State	Zip
901 S Flagler DR	WEST PALM BEACH	FL	33401
Diploma/Degree obtained, if any			
PHARM.D (Doctorat. of PHARMACY)			

School Name	From - To (MM/YY – MM/YY)		
MERCER UNIVERSITY	9/98 05/03		
Address	City	State	Zip
1501 MERCER UNIVERSITY DR	MACON	GA	30341
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name	From - To (MM/YY – MM/YY)		
Schiller ACADEMY	09/96 - 05/98		
Address	City	State	Zip
453 Edgewater DR	DUNEDIN	FL	34698
Diploma/Degree obtained, if any			
HIGH school DIPLOMA			

School Name	From - To (MM/YY – MM/YY)		
NOTRE DAME DE POISSY	10/93 - 05/96		
Address	City	State	Zip
14 Avenue Blanche de castille	Poissy (FRANCE)		
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/09 - present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: PROGESS PHARMACY			From - To (MM/YY – MM/YY): 09/06 - PRESENT	
Business Address: 8170 OKEECHOBEE BLVD #5	City: WEST PALM BEACH		State: FL	Zip: 33411
Phone: 561 720 2676	Title: OWNER / PIC			
Description of Duties: Responsible for day to day operations				

Business Name: NUBIOAGE LLC			From - To (MM/YY – MM/YY): 04/20 - PRESENT	
Business Address: 8144 OKEECHOBEE BLVD	City: WEST PALM BEACH		State: FL	Zip: 33411
Phone: 561. 223-8174	Title: CO-FOUNDER / PRESIDENT			
Description of Duties: Responsible for day to day operations				

Business Name: JUPITER MEDICAL CENTER			From - To (MM/YY – MM/YY): 01-05 - 07-07	
Business Address: 1210 S old Dixie Hwy	City: Jupiter		State: FL	Zip: 33458
Phone: 561-263-2234	Title: STAFF PHARMACIST			
Description of Duties: Dispence MEDICATION, MANAged therapies, collaborated with healthcare providers				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Franck Kacou

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/11/25

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of Palm Beach

I, FRANCK KACOU, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/11/25

Date

Subscribed and Sworn to before me this 11th day of November.

Notary Public Signature

Notary Public State of Florida
Jessica Duarte
My Commission HH 526212
Expires 5/12/2028

(Seal)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

www.FloridaHealth.gov

File # 29748
Insp # 197062

NAME	PERMIT NUMBER	DATE OF INSPECTION
CUBANCE LLC	34977	05/06/2025
DOING BUSINESS AS		
SOURCE PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
8170 OKEECHOBEE BLVD ST. 4	561-301-4220	
CITY	**COUNTY**	**STATE/ZIP**
WEST PALM BEACH	PALM BEACH	FL/33411

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9:00 am - 3:00 pm
Monday Y	Monday Hours
Tuesday Y	Tuesday Hours
Wednesday Y	Wednesday Hours
Thursday Y	Thursday Hours
Friday Y	Friday Hours
Saturday Y	Saturday Hours CLOSED
Sunday Y	Sunday Hours CLOSED

Registered Pharmacist / Intern / Tech

License # PS43590	Licensee Name Melissa Kacou
License Type Registered Pharmacists	
License # PS68076	Licensee Name Joseph William Coyne
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # Will Apply for it	

License Relations

Pharmacy Affiliate

KACOU, FRANCK	License # 42830
PASTRANA, LEONARD ERIK	License # 43440

RX DPT MGR/COR/POR

COYNE, JOSEPH WILLIAM	License # 68076

Special Sterile Compounding

CUBANCE LLC	License # 35647

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes

Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05] *Does not stock or dispense controlleds.*	N/A
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.] *Pharmacist daily record is available. Will have log with attestation when begin dispensing.*	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.] *Digital available.*	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.] *Daily and remotely monitored.*	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *Does not dispense or stock controlleds.*	N/A
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.] *Available online and hard copy.*	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.] *4/28/25*	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.] *Documented in patient profile.*	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.] *Sterile compounding only.*	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.] *All electronic records, internal bar code is assigned to product and attached to product received and traceable all the way through the system.*	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *Biopeptik*	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] *No controlled substances stocked or dispensed.*	N/A
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	N/A
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	N/A
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	Yes
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	Yes
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or heve a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications thet may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the dete of receipt, method of delivery and the neme of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between petients in this stete and e pharmacist et the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinel drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists era screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

TURIANOVERDILE, JOANNE

Date:5/6/2025

Representative:

Joseph W. Coyne

Date:5/6/2025

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

www.FloridaHealth.gov

File # 30407
Insp # 203294

NAME	PERMIT NUMBER	DATE OF INSPECTION
Cubance LLC		03/05/2025
DOING BUSINESS AS		
SOURCE PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
8170 Okeechobee Blvd Suite #4	561-834-3644	
CITY	**COUNTY**	**STATE/ZIP**
WEST PALM BEACH	PALM BEACH	FL/33411

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9am-3pm
Monday Y	Monday Hours 9am-3pm
Tuesday Y	Tuesday Hours 9am-3pm
Wednesday Y	Wednesday Hours 9am-3pm
Thursday Y	Thursday Hours 9am-3pm
Friday Y	Friday Hours 9am-3pm
Saturday N	Sunday N

Registered Pharmacist / Intern / Tech

License # PS68076	Licensee Name Joe Coyne
License Type Registered Pharmacists	
License # PS43590	Licensee Name Mellisa Kacou
License Type Registered Pharmacists	
License # RPT37122	Licensee Name Jessica Curry
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # N/A	

License Relations

Pharmacy Affiliate

KACOU, FRANCK	License #
PASTRANA, LEONARD ERIK	License # 43440

RX DPT MGR/COR/POR

COLLIER, HAYDEN WADE	License # 55063

Special Sterile Compounding

CUBANCE LLC	License # 34977

INV797 - USP Sterile Compounding
(Revision 1, USP 797 2022. August 2024)
A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *DP (JC). Role and responsibility defined in 'Introduction and Scope' policy.*	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administretion is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparetions from its original container into another container ere prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner eir and are used up to 12 hours efter initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1] *Per policy P1401 - 'BUD Stability and Determination and Stability'.*	Yes
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	Yes
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more then 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	Yes
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages ere entered or punctured only in en ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3] *Per policy P1401 - 'BUD Stability and Determination and Stability'.*	Yes
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2] *Per policy P1401 - 'BUD Stability and Determination and Stability'.*	Yes

C. CSP LABELING – ALL CATEGORIES

CSP LABEL REQUIREMENTS: CSP immediate container label prominently and legibly displays 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container (when space permits) or multi-dose container. Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *Reviewed test labels for Semaglutied subcutaneous injections during inspection - all required documentation were present.*	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) Identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING SOP: SOPs describe labeling procedures and are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *Policy p1301 'Labeling'.* ***New Pharmacy***	Yes
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13] *Policy p1301 'Labeling'.* ***New Pharmacy***	N/A

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

UNNECESSARY ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1] *Garbing and hand hygiene, correctly demonstrated by technician JC during inspection.*	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
REQUIRED PPE GARBING ORDER & STORAGE: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. Gowns and other garb are stored in a manner that minimizes contamination (e.g., awey from sinks) and within a classified area or SCA. [USP 797 Section 3.3] *Gowns, gloves and other garbing articles are stored immediately next to the sink in ISO classified Ante room. Articles are in individual packaged, and/or stored in covered plastic conteiners.*	N/A
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3]	Yes
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3]	Yes

SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3] *Per policyp0303 'Personnel Hygiene & Garbing'. However, IPA used during demonstration and stored in hood for cleaning was expired.* ***Facility not currently compounding****	No
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2] *Per policy 901 "Equipment Supplies and Components for Sterile Compounding'.*	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3]	Yes
MATERIALS AND EQUIPMENT DISINFECTION: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1 & 9.1] *Per policy P1401 - 'BUD Stability and Determination and Stability'.*	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *Per policy P1401 - 'BUD Stability and Determination and Stability'.*	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1]	Yes

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely effect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1] *Cleanroom suite certified 11-11-24.* *Ante room - ISO 8* *Buffer room - ISO 7*	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introduced through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1]	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1]	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1]	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1]	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Sections 4.2.1 & 4.5]	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *Temperature and humidity are continuously monitored by Stat Temp monitoring system.*	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the nonhazardous buffer room to anteroom and anteroom to unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *Pressure during inspection:* *Ante - (+) 0.030* *Buffer - (+) 0.032*	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3]	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

PEC & SEC CERTIFICATION: PECs are certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.4, 4.2.6, & 5.0] *PEC and SEC last certified 11-11-24 by MTA under dynamic conditions with 1 RPT, and 1 MTA Technician present.*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Certification documentation list 1 RPT, and 1 MTA Technician present.*	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Reviewed smoke study during inspection. Observe study being correctly executed.*	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *Per policy 901 'Equipment Supplies and Components for Sterile Compounding'. Devices last certified 2/3/2025.*	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. Presterilization procedures do not adversely affect the required air quality of the SEC as demonstrated during certification under dynamic operating conditions. [USP 797 Section 4.2.6] *Last certified 11-11-24*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *DP review documented in Simplifi 797.*	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3]	Yes
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Facility currently conducts Sterility testing; however no extended BUD being utilized.*	Yes
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3] *Facility does sterility testing; however Extended BUDs are not currently in use.*	Yes

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. A shorter BUD is assigned when the stability of the CSP or its components is less than the maximum BUDs stated above. [USP 797 Section 14.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	

OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2]	
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2]	
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	
PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	

MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. The training program equips personnel with the appropriate knowledge and training in the required skills necessary to perform their assigned tasks. [USP 797 Section 2] *Per policy p204 'Personnel Training & Evaluation'.*	Yes
INITIAL DIDACTIC TRAINING & SKILLS ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1] *Reviewed training documentation for Pharmacists JC, MK and technicians JC.*	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 seperate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2]	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3]	Yes
GFT & MEDIA FILL INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3] *Documentation does not show the starting temperature of each stage of incubation. However, incubator temperature monitored daily when open.*	No
ONGOING CATEGORY 1 AND 2- GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	Yes
ONGOING CATEGORY 1 AND 2- MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3]	Yes
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *Reviewed documentation for Pharmacist JC, MK, and technician JC during inspection.*	Yes
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3] *Per policy 204 'Personnel Training & Evaluation'.*	Yes
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1] *Monthly surface sampling completed by DP. Competency documented in Simplifi 797, and process outlined in policy p601, 'Microbial Air and Surface Monitoring'.*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

ONGOING CATEGORY 3 GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
ONGOING CATEGORY 3 ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *Outlined in policy p601, 'Microbial Air and Surface Monitoring'.*	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2]	Yes
AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *MTA documents calibration being completed daily.*	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3]	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3]	Yes
MEDIA INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)]	Yes

ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1] *Reviewed Trending data for November, December and January during inspection during inspection.*	Yes
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3] *No actionable growths were identified during monitoring periods reviewed. However, pharmacy took steps to ID growth during trending December analysis period.*	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused. Sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *Per policy 707 'Cleaning, Disinfecting, and Applying Sporicidal Disinfectants'.* ****Observed policy non-compliance during inspection. Open and undated bottlers of IPA and Peridox being used. Five bottles of IPA had expired manufacturer dates.*	No
DAILY PEC CLEANING & DISINFECTION WITH STERILE AGENTS: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. Sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7] *Cleaning document in Simplifi 797.*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7] *Facility uses Peridox for daily cleaning.*	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chembers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2 -MONTHLY PEC, SEC & SCA SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. SCA ceilings (if applicable) are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7] *Per policy 707 'Cleaning Disinfecting & Applying Sporicidal Disinfectants'.*	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7]	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2]	Yes

FACILITY COMPOUNDS CATEGORY 3

WEEKLY SPORICIDAL CLEANING OF PECs & SECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's, on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to storage shelving and bins, equipment outside of PEC's, sink surfaces, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6] *Pre-sterilization occurs ISO 8 classified Ante room.* **Last certified 11-11-25.*	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *Per policy p901 'Equipment Supplies, and Components for Sterile Compounding'.*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1] *Reviewed testing completed 12/4/25 during inspection. Results were consistent with manufacturers. No defects were found.*	Yes

API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *API procurred from Biopeptic, PCCA, Medisca.*	Yes
COMPONENT STORAGE: Components are handled and stored in a manner thet prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4]	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogeneted. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1] *Reviewed documentation for the sterilization of bottles flip caps and rubber stoppers during inspection.*	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unaccaptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2] *Per policy p901 'Equipment Supplies, and Components for Sterile Compounding'.* *- Receipt documented in Simplifi, and approved / rejected by DP.*	Yes
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *No CSP currently being terminally sterilized.*	N/A

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and heve enough capacity to filter the required volumes. [USP 797 Section 10.2] *Pharmacy uses MDI Aseptic Cap 0.2 micro filters Advance by Advanced Microdevices.*	Yes
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Reviewed integrity test completed on 12/4/25 during inspection.*	Yes
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2]	N/A
CSP TERMINAL STERILIZATION SOP Includes: 1) A description of CSP terminal sterilization process(es), including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization methods and equipment. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10]	N/A
STEAM OR DRY HEAT STERILIZATION CYCLES FOR CSPs: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. CSPs sterilized vial steam are placed in the autoclave to allow steam to reach CSPs without entrapment of air. CSPs sterilized via dry heat are placed with sufficient space between materials to allow for hot air circulation. Sterilization cycle parameters (e.g., temperature, pressure, and duration) and load configuration(s) are documented. [USP 797 Section 10.3 & 10.4] *New Pharmacy.*	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of steam or dry heat sterilization of CSPs is verified and documented for each sterilization run or load by using appropriate biological indicators (e.g., Geobacillus stearothermophilus for steam, Bacillus atrophaeus for dry heat) and other confirmation methods. [USP 797 Section 10.3]	N/A
STEAM & DRY HEAT CSP PREFILTRATION: Immediately before filling containers that will be sterilized vie steam, or dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each steam or dry heat sterilization cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). The calibrated oven is equipped with temperature controls and a timer. [USP 797 Section 10.3 & 10.4] *New pharmacy. No compounding currently being conducted.*	N/A

R. STERILIZATION & DEPYROGENATION OF SUPPLIES & CONTAINER CLOSURE SYSTEMS - CATEGORY 2 & 3

STERILIZATION & DEPYROGENATION SOP's Include: 1) A description of sterilization and depyrogenation process(es) used to sterilize and/or depyrogenated compounding supplies and container closure systems, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. [USP 797 Section 10] *Policy p902 'Autoclave Loading and Maintenance'.*	Yes
DEPYROGENATION VIA DRY HEAT: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1 & USP 1228.4]	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are sterilized via a validated sterilization method and cycle: these items are also depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section 10 & 10.1]	N/A
DEPYROGENATION PROCESS VALIDATION: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using Endotoxin Challenge Vials (ECVs) to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the cycle parameters . Cycle verifications are documented. [USP 797 Section 10.1] *Reviewed challenged completed on 11/19/24, with Max Beaker Load pic/diagram during inspection.*	Yes
STERILIZATION CYCLE VALIDATION: When performed onsite, the efficacy of sterilization cycles used for supplies or container closure systems are established and documented. Each sterilization run or load is verified and documented by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 9.3.1 & USP 1229] *Reviewed documentation for Autoclave Load for efficacy validation completed on 1/20/25 during inspection.*	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient and any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *Per policy p1101 'Master Formulation & Compounding Records'.*	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *Reviewed a MFR for Tirzepatide 10mg/mL with L-Carnitine 500mcg/mL 5mL during inspection.* *Pharmacy design has MFR become the CR with and assigned lot number and a barcode.*	Yes
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2]	Yes
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *Pharmacy uses Pharmetika system to assign and link sterilization barcode to the CR.*	Yes

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12]	Yes
VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Per policy p1201 CSP Release Inspections Testing.*	Yes
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *Per policy p1201- 'CSP Release Inspections & Testing'.*	Yes
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1]	Yes
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1]	Yes

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. [USP 797 Sections 9.3 & 19.1] *Temperature monitored continuously Stat Temp monitoring system. Daily checks documented in Simplifi.*	Yes
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2] *Per policy 1902 'Handling, Storage, Packaging, Shipping & Transport'.*	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *Per policy 1902 'Handling, Storage, Packaging, Shipping & Transport'.*	Yes

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *Per policy p1803 'Quality Assurance and Quality Control'.*	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *Per policy p1803 'Quality Assurance and Quality Control'.* ****New Facility****	N/A
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *Per policy 'p1801 - Quality Assurance Control'.* ****New Facility****	N/A
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18] *Per policy p1803 'Quality Assurance and Quality Control'.*	Yes

ANNUAL SOP & QA/QC COMPLIANCE REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 17 & 18] ****New Pharmacy**** *Policies last reviewed 12/31/24*	N/A

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4]	
HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8]	
LIST OF HAZARDOUS DRUGS & ASSESSMENT OF RISK: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must documents what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation considerations. The HD drug list & AOR is reviewed at least every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2]	
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1]	
HD HANDLING, RECEIPT & STORAGE SOPs: SOPs are created and followed for the safe handling of HDs used by the facility. [USP 800 Section 17]	
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, storage, and sterile compounding of HDs. [USP 800 Section 5]	
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2]	
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated has 30 ACPH, and negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Section 5.3.2 Table 3]	
C-SEC ACCESS: The Ante Room used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. Alternatively, a negative-pressure HD buffer entered exclusively through a positive pressure non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2]	
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2]	
C-PEC LOCATION, VENTING, & OPERATION: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. C-PECs operate continuously if supplying some or all the negative pressure in the C-SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3.2]	
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free and two pair of chemotherapy gloves are donned per SOP. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding garment. When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. Reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7]	
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	
HD TRAINING & COMPETENCY ASSESSMENT: Personnel who handle HDs are trained and demonstrate competency initially before independently handling HDs, annually, and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17]	
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 5.3.2 and Table 3]	

DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): Areas where HDs are handled and all reusable equipment and devices are deactivated/decontaminated, and cleaned. Sterile compounding areas and devices are subsequently disinfected. Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15]	
D/D/C/D TRAINING & PPE REQUIREMENTS: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. [USP 800 Section 15]	
C-PEC D/D/C/D: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. The area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2]	
HD LABELING, PACKAGING, TRANSPORT & SPILLS HANDLING: Facility follows SOP for the labeling, handling, packaging, and transport of HDs which addresses the prevention of spills/exposures, training for exposure, and spill handling. HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Section 11 & 11.2]	
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas, restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenence of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the esteblished visuel criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure menual and quarterly summarizetion of Quelity Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(i) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	

All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Z. Miscellaneous

BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	
ALLERGENIC EXTRACTS: Licensed allergenic extracts are mixed and diluted to prepare prescription sets for administration to patients. A prescriptions set is a vial or set or vials of premixed licensed allergenic extracts for subcutaneous immunotherapy that have been diluted with an appropriate diluent for an individual patient. Compounding allergenic extracts 1) minimally complies with all aspects of USP <797> Section 21; 2) involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and 3) manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials. If these conditions are not met, compounding of allergenic extracts follows all aspects of USP <797>. [USP 797 Sections 1.1.2 and 21]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

MURRAY, CHARLENE

Date:3/5/2025

Representative:

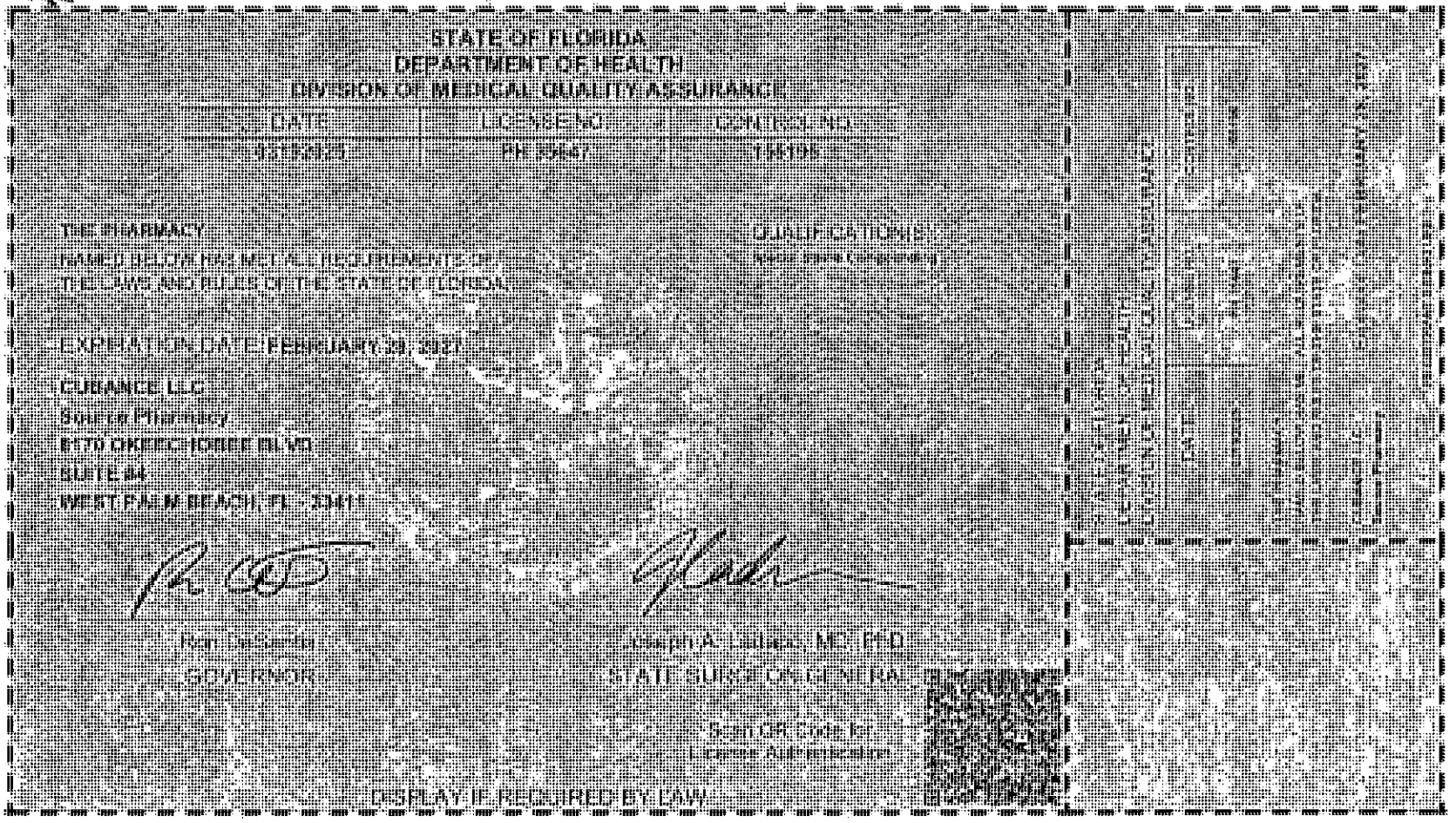
Joseph W. Coyne

Date:3/5/2025

Your license number is PH 35647.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.



STATE OF TENNESSEE

DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
DIVISION OF HEALTH RELATED BOARDS

665 Mainstream Dr.
Nashville, TN 37243

tn.gov/health

TENNESSEE BOARD OF PHARMACY
(615) 253-1299 or (615) 741-2718

November 6, 2025

TO WHOM IT MAY CONCERN:

This letter serves as primary source verification of licensure in the State of Tennessee. To expedite the verification process, this is the standard format used by the Board of Pharmacy. The Board of Pharmacy is pleased to furnish the following information from our files:

PROFESSION:	Pharmacist
RANK:	Pharmacist
NAME:	Brown, Gregory A
LICENSE NUMBER:	49496
ISSUE DATE:	11/04/2025
EXPIRATION DATE:	11/30/2027
CURRENT STATUS:	Licensed
STATUS DATE:	11/04/2025
SPECIAL ENDORSEMENTS:	Controlled Substance Qualifications

COMMENTS: There is no history of disciplinary action on this license. The State of Tennessee only provides the above information. Any other information needed must be obtained from the licensee.

Sincerely,

Tennessee Board of Pharmacy

November 3, 2025

Cubance Llc
8170 Okeechobee Blvd, Suite #4
West Palm Beach, FL 33411

RE: License Certification for Cubance Llc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH35647
ORIGINAL CERTIFICATION:	03/18/2025
EXPIRATION DATE:	02/28/2027
CURRENT STATUS OF LICENSE:	Clear,
AGENCY ACTION:	No
LICENSE GRANTED BY:	N/A
OTHER CERTIFICATIONS:	Special Sterile Compounding

To expedite the verification process, the above format is the standard format for all license certifications. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Michelle Burns

Michelle Burns
Operations and Management Consultant Manager

Department of Health

License Verification

Printer Friendly Version

GREGORY ALLEN BROWN

License Number: PS40549

Data As Of 10/9/2025

License Information | Secondary Locations | Discipline/Admin Action

Profession	Pharmacist
License	PS40549
License Status	Clear/Active
Qualifications	Certified To Administer Immunizations
License Expiration Date	9/30/2027
License Original Issue Date	09/19/2005
Address of Record	300 Northpoint Parkway Suite 301 WEST PALM BEACH, FL 33407
Discipline on File	No
Public Complaint	No

Back

For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.

Primary Source Verified

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CUBANCE LLC

SOURCE PHARMACY

License Number: PH34977

Data As Of 10/7/2025

Profession	Pharmacy
License	PH34977
License Status	Clear/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2027
License Original Issue Date	02/12/2024
Address of Record	8170 OKEECHOBEE BLVD ST. 4 WEST PALM BEACH, FL 33411
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
COYNE, JOSEPH WILLIAM	RX DPT MGR/COR/POR	PHARMACIST	68076	01/06/2025
CUBANCE LLC	PHARMACY	PHARMACY	35647	12/06/2024

Name	Relationship	Profession	License	Effective Date
KACOU, FRANCK	PHARMACY AFFILIATE	PHARMACIST	42830	01/18/2024
PASTRANA, LEONARD ERIK	PHARMACY AFFILIATE	PHARMACIST	43440	01/18/2024

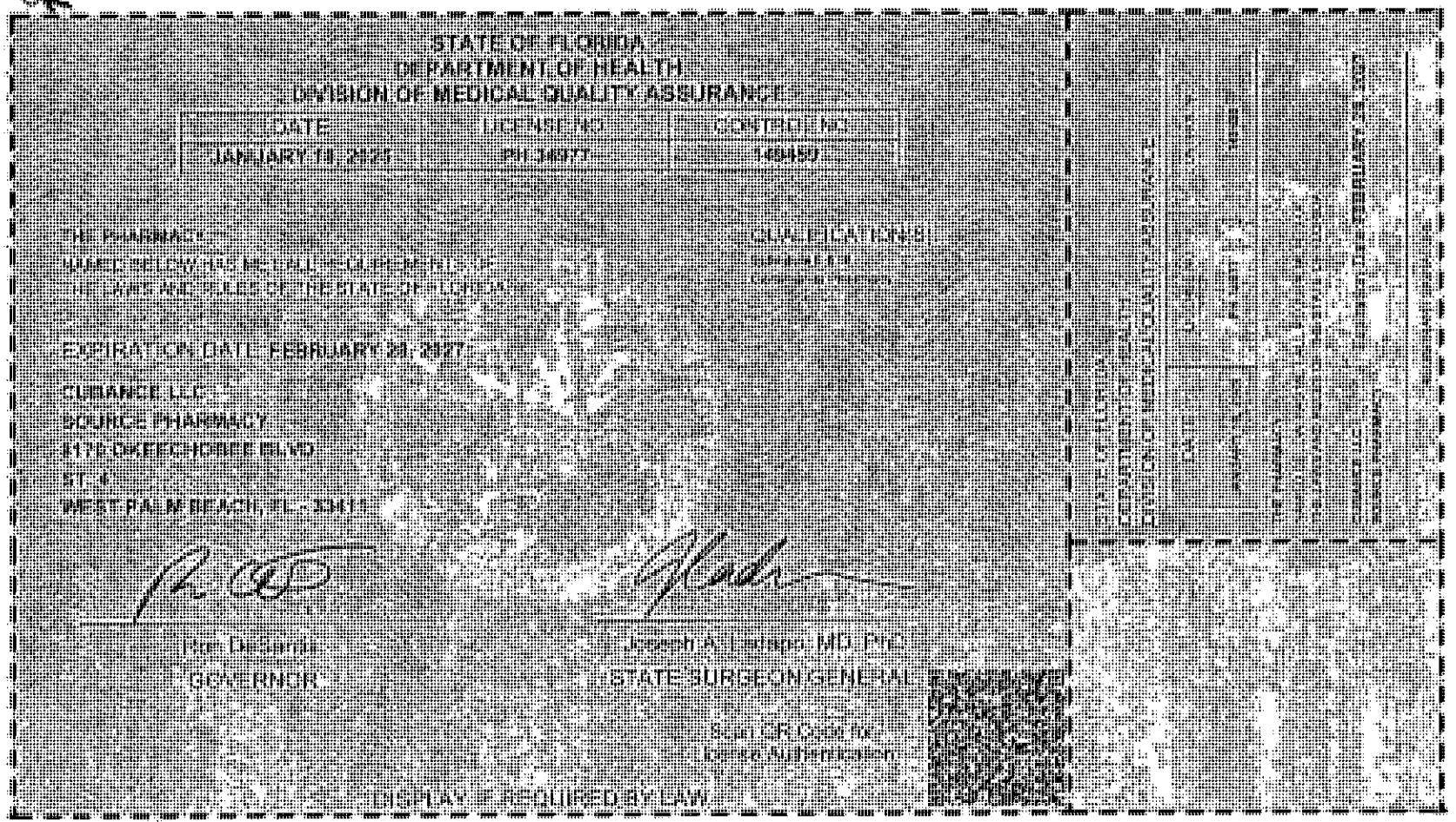
Click on the License Number to view License Details for that Practitioner

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
JANUARY 19, 2023	PH 34977	149450

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THE LAWS AND RULES OF THE STATE OF FLORIDA

EXPIRATION DATE: FEBRUARY 28, 2027

CURANCE LLC
SOURCE PHARMACY
6176 OKEECHOBEE BLVD
STE 4
WEST PALM BEACH, FL 33411

QUALIFICATIONS

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Cubance LLC dba Source Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 8170 Okeechobee Blvd, Suite 4

City: West Palm Beach State: FL Zip: 33411

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 855-437-7316 Toll Free # (NAC 639.708, NRS 639.23286): (855) 437-7316

Fax: (561) 666-4018 Contact Email: licensing@sourcerxpharmacy.com

Website: https://sourcerx.health/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Gregory Allen Brown

Supervising/Managing Pharmacist NV Pharmacist Registration #: _____

Name of Designated Person(s) as defined by revised USP-797 guidelines: Joseph Coyne

Email of Designated Person(s): licensing@sourcerxpharmacy.com

Telephone of Designated Person(s): 215-850-1495

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

■ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 11/7/2025

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Semaglutide with cyanocobalamin
Tirzepatide with cyanocobalamin
Semaglutide with glycine
Semaglutide with levocarnitine
Pentosan polysulfate
Procaine

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway Suite 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 800-393-1595

13. What is your procedure for visual inspection of compounded sterile products?
All CSPs are visually inspected against a black and white background as part of the compounding process. Any product not immediately dispensed is again visually inspected before dispensing. SOP P-1201.1 details this process.

14. How often do you perform glove fingertip and medial fill testing?
Upon hire and every 6 months for compounding personnel. SOP P-0204.1 details complete personnel training and competencies.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
SOP P-0204.1 provides complete detail and is attached for reference.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
SOPs: P-0701.1; P-0702.1; P-0703.1 covers daily, monthly, and remedial cleaning procedures, agents, etc. and are attached for reference.

17. Who performs the sterile compounding process at your facility?

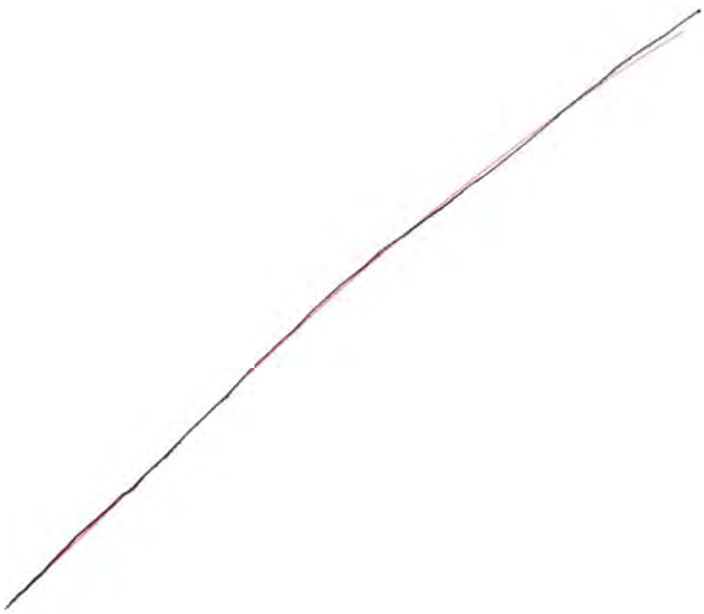
Only personnel who have been properly trained and completed the required competencies

18. Who is responsible and accountable for the sterile compounding process at your facility?
The Designated Person, Joseph Coyne

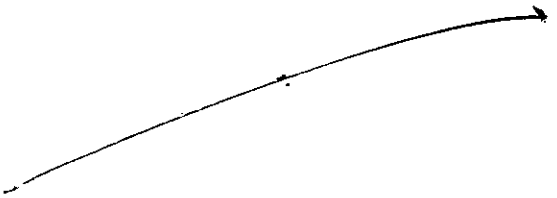
19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Out of state packaging and shipping SOP 1905.1 and P-1904.1 maintaining shipping integrity details these procedures and are included.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?



11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?



N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:



2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?



3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?



5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐Yes	☐No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐Yes	☐No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Franck Kacou

Name of Person who Completed the Form

CEO/Owner

Title

Signature (copies or stamps not accepted)

11/11/25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Section Name: Release Inspections & Testing	Policy Name: CSP Release Inspections & Testing
Policy Number/ Version: P-1201.1	Last Revision/Review Date: 12/31/2024

1. Overview and Scope

a. This policy describes the procedures for Compounded Sterile Preparations (CSP) release inspections, quality control testing, and final verification of CSPs prepared within Source Pharmacy.

b. Release inspections and testing are an important component of product quality control measures and the final verification of CSPs prior to release and dispensing. Release inspections and testing includes, but is not limited to:

   i. **Visual inspections** – physical product characteristics, labeling, container closure system.

   ii. **Quality control tests** – pH, tonicity (osmolarity), refractive index, sterility, endotoxin level .

   iii. **Physical measurements of final CSP / batch yield** – weight and/or volume.

   iv. **Calculations and conversions verification.**

c. This policy addresses the release inspection and testing requirements stated in the current version of USP <797> and in accordance with the Florida State Board of Pharmacy and related state statutes governing sterile compounding.

2. Policy

a. Release inspections of and tests on CSPs are performed by:

   i. Compounder during and immediately after compounding.

   ii. Verifying Pharmacist conducting in-process and/or final CSP verification and sign-off prior to release and dispensing.

   iii. Pharmacist prior to release and dispensing if CSP is released and dispensed more than 24 hours after completion of compounding.

b. CSPs undergo visual inspection prior to release and dispensing to ensure preparation has no visual defects and its appearance meets expectations as characterized in the manufacturer's labeling, Master Formula Record (MFR) or Pharmetika (IV Workflow System).

c. CSP labeling is visually inspected and compared to the prescription or medication order to ensure accuracy. Label positioning is checked to ensure important device measurements and manufacturer labeling and product identification is not obstructed.

d. CSP container closure systems (i.e., final dispensing container and packaging) are visually inspected to ensure they are free of leaks, cracks, improper seals, and other defects that could affect sterility, stability, or CSP quality.

e. CSPs with observed defects are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal occurs. Appropriate disposal of the rejected CSP according per policy **(P-1903)**.

f. When CSPs are not released or dispensed on the day of preparation and verification, a visual inspection of the preparation, label, and container closure system occurs immediately before it is released or dispensed. Attention is given to defects that occur during storage including precipitation, cloudiness, separation/loss of homogenity, or leakage.

g. CSPs compounded at Source Pharmacy are not released or dispensed prior to the successful completion and documentation of required release inspections and tests.

h. CSPs are quarantined until pending release test results are known including, but not limited to, the following quality control tests performed on site by qualified personnel and/or analytical laboratories:

   i. Sterility Testing (per USP <71> standards).

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ii. Endotoxin Testing (per USP <85> standards).
iii. Antimicrobial Effectiveness Testing (per USP <51> standards).
iv. Pending CSP, component, or container closure sterilization cycle and/or load validation results (per USP <1229> & related Chapters).

i. CSP defects indicating sterility or stability issues which are detected prior to release or dispensing are investigated to determine the cause of the defect(s) and corrective actions are taken if appropriate. During the investigation, CSPs are quarantined pending the outcome. Results of the investigation, corrective actions, and disposition of the quarantined CSPs are documented and readily retrievable.
j. Compounding Personnel who perform release inspections and testing receive foundational knowledge education, hands-on training and skills development, and undergo an observed competency assessment prior to performing job duties independently.
   i. Ongoing training and education are provided when new or modified release criteria are introduced and at the discretion of the Designated Person(s).
   ii. Ongoing competency assessment is successfully completed at least once annually.
   iii. Documentation of training and competency assessments is retained and readily retrievable.

3. Roles & Responsibilities

a. Designated Person(s) (DP):

i. Determine appropriate release inspections and tests for CSPs and ensure release criteria, procedures, and documentation requirements are clearly described in internal references, the Master Formula Record and/or IV Workflow System.
ii. Ensure personnel conducting release inspections and tests receive appropriate education and training and undergo competency assessment on the skills and techniques necessary to successfully perform these techniques prior to performing them independently and on an ongoing basis.
iii. Identify, vet, and partner with analytical labs and release inspection and testing supply and equipment vendors.
iv. Review release inspection and testing results and trends. Identify deficiencies, oversee investigations and corrective actions, and ensure proper documentation.
v. Ensure release inspection and testing data is accurately and fully documented.

b. Compounding Personnel:

i. Comply with all aspects of the release inspection and testing requirements for each CSP.
ii. Ensure complete, accurate, and timely documentation of release inspection and testing results per this policy.
iii. Report known or suspected deficiencies in the equipment, supplies, or vendors used in release inspections and testing to the DP.
iv. Report CSP release inspection failures to the DP and quarantine products in a timely manner per this policy.

c. Verifying Pharmacist:

i. Perform double check of all calculations, measurements, and conversions.
ii. Conduct final visual verification of CSP, label and container closure system.

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4. Procedures

a. CSP Release Inspection & Test Determination

i. Identify required release inspections and tests for each CSP, formulation, and/or container closure system.

Required	Category	Release Inspection or Test
All CSPs	Visual Inspections	1. **CSP Final Prep**: free of visible particulates, foreign matter, or precipitate; discoloration; homogeneity of mixture (no separation); viscosity and characteristics 2. **CSP Label(s)**: match to prescription or med order, placement (not covering device or diluent product name and id or calibrated measures) 3. **CSP Container Closure System**: leaks, cracks in packaging or seals, deformities impacting dispensing.
Category 2 CSPs *Per dosage form, formulation, & route of admin*	Physical & Chemical Tests and Measures	1. **Physiochemical Tests**: pH, osmolarity, refractive index, specific gravity 2. **Physical Measures**: weights, volumes, temps
	Calculations & Conversions	1. **Calculations**: component weights and volumes based on final target yield; additional yield quantity needed for required testing; specific gravity 2. **Conversions**: salt form, strength and/or purity margin of error, pharmaceutical unit to measurable unit
Category 2 CSPs *With longer BUDs*	CSP Sterility Testing	Required for each CSP batch per USP <71>* NOTE: Method Suitability Testing required once per formulation (or bracketed formulation) prior to conducting USP <71> testing
Category 2 CSPs *Requiring sterility testing & from nonsterile components*	CSP Endotoxin Testing	Required for each CSP batch per USP <85>*
Category 2 CSPs *From nonsterile components*	Sterilization Cycle Results	Required for each CSP batch compounded from nonsterile ingredients and sterilized per USP <1229> and subchapters (including <1229.5>) *
Category 2 CSPs *For preserved aqueous dosage forms*	Preservative Effectiveness Testing	Required once per formulation and fill volume in the specific container closure system per USP <51>**
Category 2 Multi-dose CSPs	Container Closure System Testing	Required once for each unique container closure system per USP <1207>*

** Alternative methods are allowed if validated and noninferior to the referenced Compendial Procedure.*
***Results from an FDA-registered facility or published in peer-reviewed literature sources are allowed in lieu of USP <51> Antimicrobial Effectiveness Testing, provided that the CSP formulation (including any preservative) and container closure system are exactly the same as those tested, unless a bracketing study is performed.*

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ii. Determine specific physical and chemical release inspections, tests, and expected results for each CSP formulation by referring to USP-NF drug monographs, internal resources, or other recognized sterile compounding formulation and stability resources. CSP release inspections and tests for sterile dosage forms include the following adapted from Table 2 of USP <1163> Quality Assurance in Pharmaceutical Compounding:

	Injection	Irrigation	Inhalation	Ophthalmic
Visual Particulate Matter	✓	✓	✓	✓
Weight	✓	✓	✓	✓
Volume	✓	✓	✓	✓
pH	✓	✓	✓	✓
Osmolarity	✓	✓	✓	✓
Refractive Index	✓	✓	✓	✓
Specific Gravity	✓	✓	✓	✓
Melting Point				
UV/Visible Spectroscopy	✓	✓	✓	✓
HPLC (High Performance Liquid Chromatography)	✓	✓	✓	✓
Gas Chromatography	✓	✓	✓	✓
Potency	✓	✓	✓	✓
Sterility	✓	✓	✓	✓
Endotoxin	✓	✓	✓	
Loss Upon Drying	✓			

iii. Considerations for selecting and defining release criteria procedures and expected results:
   a. CSP Category.
   b. Compatibility and appropriateness of release inspections, tests, and testing apparatus/supplies for the given CSP formulation, dosage form, and final drug yield
   c. CSP stability under testing conditions.
   d. Potential for final CSP and/or route of administration to cause patient harm (e.g., intrathecal versus intramuscular injection).
   e. Additional regulatory and statutory requirements.
   f. Number/quantity of sample(s) needed for testing and the impact to the total compounded quantity or yield.

iv. Document selected release inspections and testing requirements, including procedures, testing apparatus, and expected results in the appropriate system and/or formulation record for each CSP including:
   a. **Master Formula Record (MFR)** - for CSPs compounded from one or more nonsterile starting ingredients or repackaged CSPs
   b. **IV Workflow Management System (IVWS)** or similar.
   c. **Compounding System (CS)**.

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b. CSP Release Inspections & Testing

i. Conduct the specific release inspections and testing defined for each CSP according to the MFR, IVWS, or CS procedures and instructions.

c. Visual Inspections - Liquid Dosage Forms

i. Wipe the container closure system with a damp, lint-free wipe to remove any external particles.
ii. Gently agitate and/or swirl the CSP, with a light source shining behind or under the CSP and hold in front of both a black and white background.
iii. Observe for color, clarity, precipitate/foreign matter, phase separation, etc. Use magnifying glass if needed.
iv. Reject CSP if any deviations are observed and document results on CR, IVWS, or CS.

d. Visual Inspections - Semi-Solid & Solid Dosage Forms

i. Prior to terminal sterilization or placement in final container closure system:
    a. Visually inspect CSP dosage forms for shape, color, homogeneity, size, surface characteristics (e.g., smoothness, shine or mat finish).
    b. Reject CSP if any deviations are observed and document results on CR, IVWS, or CS.
ii. After terminal sterilization (if container closure system is not opaque or tinted):
    a. Wipe the container closure system with a damp, lint-free wipe to remove any external particles.
    b. Hold CSP above or in front of a light source and inspect CSP for shape, color, size, and surface characteristics.
    c. Reject CSP if any deviations are observed and document results on CR, IVWS, or CS.

e. Weight of Semi-Solid or Solid Dosage Forms

i. Zero or tare analytical balance with weigh paper/boat (or similar).
ii. For single dose CSP:
    a. Weight CSP and compare weight to excepted or theoretical weight and determine the percent deviation. Acceptable deviation is + 10% unless otherwise specified in the MFR, IVWS, or CS.
    b. Reject CSP if deviation exceeds the acceptance parameter; record results and percent deviation on/in the CR, WS, or CS.
iii. For multiple dose (batched) CSPs:
    a. Weigh a representative sample of the finished batch 10% or 10 individual units whichever is greater.
    b. Record weights of each sample and calculate the mean of the total samples.
    c. Compare individual and mean weights to excepted or theoretical weight and determine the percent deviation. Acceptable deviation is +5% unless otherwise specified in the MFR, IVWS, or CS.
    d. If an individual CSP weight deviation exceeds the acceptance parameter, reject the individual CSP and repeat entire process with a new batch of CSPs. If additional single CSPs exceed the weight deviation parameter, quarantine the batch and consult with the DP for next steps.

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e. If the mean weight of the sampled CSPs exceeds the acceptance parameter, quarantine the batch and consult with the DP for next steps.
f. Record all results, percent deviations, and outcomes on/in the CR, WS, or CS.

f. Volume of Liquid Dosage Forms

i. If density of the CSP is known, volume (in milliliters) is calculated by measuring the mass of the liquid in grams (less the dry weight of the container) and divided by the density.
ii. For liquid dosage forms not in a final container closure system (pre-sterilization):
   a. Transfer the full CSP volume to a graduated cylinder designed for volumetric measurements not exceeding 40% of the total volume to be measured. Use proper technique to observe the meniscus and record results on the CR, WS, or CS.
   b. Acceptable deviation is + 5% unless otherwise specified in the MFR, IVWS, or CS.
   c. Reject CSP if deviation exceeds the acceptance parameter; record results and percent deviation on/in the CR, WS, or CS.
iii. For Small Volume Single Dose Containers, Cartridges, or Prefilled Syringes (< 100 mL):
   a. With a dry syringe (or similar) assembly, draw up entire contents of the container (if appropriate).
   b. Remove air bubbles and transfer to an appropriately sized graduated cylinder.
   c. Alternatively, remove the stopper or closure device of the container (or syringe) and transfer solution into a graduated cylinder.
   d. Acceptable deviation is + 5% unless otherwise specified in the MFR, IVWS, or CS.
   e. Reject CSP if deviation exceeds the acceptance parameter; record results and percent deviation on/in the CR, WS, or CS.
iv. Additional considerations:
   a. For batched small volume, single-dose containers, sample a representative number.
   b. If individual volumes are < 2 mL per container, multiple containers can be pooled and measured.
v. For Multi-dose Containers:
   a. With a dry syringe assembly, draw up the entire contents of the container.
   b. Remove air bubbles and transfer to an appropriately sized graduated cylinder.
   c. Alternatively, using individual dose appropriate syringes, precisely draw up the number of doses in the container.
   d. Acceptable deviation is + 5% unless otherwise specified in the MFR, IVWS, or CS.
   e. Reject CSP if deviation exceeds the acceptance parameter; record results and percent deviation on/in the CR, WS, or CS.
vi. For Large Volume Solutions (> 100 mL):
   a. Open one large volume container and transfer to a volumetric cylinder (not exceeding 40% of the total volume to be measured).
   b. Acceptable deviation is + 5% unless otherwise specified in the MFR, IVWS, or CS.
   c. Reject CSP if deviation exceeds the acceptance parameter; record results and percent deviation on/in the CR, WS, or CS.

g. pH Determination

i. Calibrate pH meter prior to use.
   a. Calibration with an ATC/Temp probe in the pH-AUTOLOCK Mode)

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b. Turn the unit on. In pH mode, press "**Clear**" key for 5 seconds, all LCD elements will lit up. The meter clears all calibration values stored in internal memory.
c. Connect the pH electrode to the BNC connector and the ATC/Temp probe to the ATC/Temp connector of the unit: "**ATC**" icon will lit up. "**pH**" icon and "**AUTO**" icon will lit up. The "**CAL**" icon begins to flash.
d. Rinse the pH and ATC/Temp probes in distilled water and immerse them in the first buffer solution. Allow temperature reading to stabilize, then press and hold "**Stand**" key for 2 seconds to calibrate. The "**WAIT**' icon will flash until the unit
e. detects a stable reading. Once the unit calibrates the first point, the selected buffer will lit up while two other selectable buffers start to flash. The unit is ready to be sloped at the 6 second buffer. [Note: If the first buffer solution is 7.00 or 6.86 pH, at this moment, press the "**Mode**" key. The unit will exit the calibration mode. Single point calibration is complete. If the first buffer solution is 1.68, 4.00, 4.01, 9.18, 10.01 or 12.46 pH, at this moment, the unit will automatically exit the calibration mode. Single point calibration is complete].
f. Rinse the pH and ATC/Temp probe in distilled water and immerse them in the second buffer solution (either 4.00 / 4.01 pH or 9.18 / 10.01 pH corresponding to the flashing number on display). Allow temperature reading to stabilize, then press "**Slope**" key to calibrate. The "**WAIT**" icon will flash until the unit detects a stable reading. Once the unit calibrates the second point, the selected two buffers lit up and the remaining buffer starts to flash. The unit is ready to be sloped at the third buffer. [Note: At this moment, press the "**Mode**" key, the unit will exit the calibration mode. Dual point calibration is complete.]
g. The third point, the fourth point and the fifth point are the same as the second calibration point. When the unit completed the fifth point calibration, press the "**Mode**" key and exit calibration.
h. The unit calculates and compensates for the pH electrode slope deviation corresponding to the values of the calibrated buffers. After calibration, press and hold "**Mea./Eff.**" key for about 5 seconds to display the new electrode efficiency and
i. offset.

ii. Measurement with an ATC/Temp probe in the pH AUTOLOCK mode.
a. Connect the pH electrode to the BNC connector and the ATC/Temp probe to the ATC/Temp connector of the unit. The "ATC" icon will lit up.
b. Press "**Mode**" key until "**pH**" icon and "**AUTO**" icon lit up.
c. Rinse the pH electrode and ATC/Temp probe with distilled water and immerse in the sample to be measured. Remove any air bubbles trapped around the probe by shaking or stirring the probe.
d. Press the "**Mea. / Eff.**" key. The "WAIT' icon will start flashing. The unit is waiting for a stable reading. The display will track the pH value as sensed by the pH electrode and the ATC/Temp probe.
e. When the '**WAIT**" icon disappears, the reading is then "**LOCK**" and will not respond to further changes from the sample. The pH value shown is the pH value of the sample at the displayed sample temperature.

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f. [**Note:** For samples that are inherently unstable, the unit will not AUTOLOCK. In this case, use the pH NON- AUTOLOCK mode for measurements]. Record buffer solutions used, solution temperatures, and final CSP pH reading on/in the CR, IVWs, or CS.

iii. Reject CSPs exceeding the acceptable pH range or +0.5 of the expected pH for the formulation.

iv. Reject CSP if deviation exceeds the acceptance parameter; record results and percent deviation on/in the CR, WS, or CS.

Release Inspection or Test	Laboratory Name & Contact Information	Sample Preparation, Chain of Custody & Submission Paperwork & Shipping Instructions
Potency Testing	Eagle Analytics	Per protocols provide by Eagle Analytics
Sterility Testing	Eagle Analytics	CSP Sterility and Bacterial Endotoxin Testing policy **(P-1401)** for related procedures
Endotoxin Testing	Eagle Analytics	

h. Specific Gravity (SG)

i. Calculate the specific gravity (unitless ratio) of a substance by either of the following:

a. SG = (density of substance) / (density of water at 4°C) [(g of substance/mL)/ 1.00 g/mL] ***OR***

b. SG = (weight of substance in grams) / (density of an equal volume of water in mL) at a given temperature.

i. Outsourced Release Inspections and Tests

i. Use an outsourced laboratory for the CSP release inspections or tests.

j. CSP Calculations and Conversions

i. Using information obtained from USP-NF monographs, Certificate of Analysis for Active Pharmaceutical ingredients, or other internal and accepted sterile compounding reference sources, perform the required calculations and conversions required to ensure accurate measurements of components and preparation of desired CSP concentration.

ii. Refer to USP <1160> - Pharmaceutical Calculations in Pharmacy Practice or similar peer reviewed pharmacy calculations resource to obtain accurate and appropriate formulas and calculation instructions if not available in the MFR, IVWS, or CR.

iii. Document all calculations and conversions on/in the CR, IVWS, or CR including double check of the same.

k. Documentation and Follow Up to Release Inspections and Testing

i. Document actual and expected (if applicable) release inspection and test results on the CR, IVWS, or CS.

ii. Reject CSPs failing or not achieving expected results and quarantine CSPs.

iii. Ensure rejected CSPs are stored in a clearly marked area to ensure CSPs are not accidentally released or dispensed.

iv. Promptly report release testing failure(s) to DP for determination if additional processing, retesting, investigations, and/or corrective actions are warranted.

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l. **Quarantine of CSPs Pending Release Testing Results**
   i. Define segregated and visibly labeled product quarantine areas or bins within the controlled compounding area in each of the temperature monitored storage conditions:
      a. Controlled Room Temperature: 20°C - 25°C (59° to 72° Fahrenheit).
      b. Refrigerator: 2°C - 8°C (36° to 46° Fahrenheit).
      c. Freezer: -25°C to -10°C (-13° to 14° Fahrenheit).
   ii. Quarantine CSPs in the designed area per its respective labeled storage requirements to maintain stability and sterility pending release testing results that require longer than 2 hours to finalize and/or review.
   iii. Document CSPs on Quarantine Log; refer to **F-1201** CSP Quarantine Log.
   iv. Package and Label quarantined CSPs prior to placement in quarantine storage with the following information to reduce the risk of mixing up multiple simultaneously quarantined CSPs:
      a. Start Date of Quarantine.
      b. Person Placing CSP(s) in Quarantine.
      c. Reason for Quarantine (e.g., Pending sterility or endotoxin test results from lab).
      d. Anticipated Quarantine Duration.
   v. After release test results have been received and reviewed, log the quarantine outcome on the Quarantine Log and the compounding record for the respective CSP(s)
   vi. If the CSP(s), pass the release tests:
      a. Remove CSPs from quarantine area and place in the pre-dispensing stock location for the CSP within the controlled area of the pharmacy.
      b. Prior to release and dispensing, apply the dispensing label (if not done previously) and conduct a visual inspection of the CSP and container closure system for signs of product degradation or loss of container integrity.
   vii. If CSP(s) fail release tests or final dispensing visual inspection, reject and dispose of CSP per policy.

m. **Final CSP Verification**
   i. Refer to Workflow **(P-0801)** and Aseptic Technique policy **(P-0201)** for the CSP final verification procedure.

5. Definitions

a. **Acceptance Quality Limit (AQL):** The maximum number of defective units allowed; beyond which the entire batch is rejected.
b. **Batch:** A specific quantity of CSPs prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
c. **Container closure system:** Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components if the latter are intended to provide additional protection.
d. **Formulation:** The specific qualitative and quantitative composition of the final CSP.
e. **Meniscus:** The lowest point of the curvature of a liquid's surface inside of graduated cylinder and the point at which liquid measurements are determined.

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f. **MFR:** Master formulation record.
g. **Monograph:** A quality documentary standard within USP-NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
h. **Quality control (QC):** The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
i. **Release inspection and testing:** Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
j. **Refractive index (RI):** A physical property characterizing the ability of substance to "bend" or refract light. The refractive index is the measure of the solute concentration of a substance or CSP and is used to help determine uniformity and conformance with a known RI value.
k. **Specific Gravity (SG):** A unitless ratio of the density of a substance to the density of water at 4°, or [(g of substance/mL)/ 1.00 g/mL]. If known, can be used to help calculate density, volume, or weight of a substance.
l. **Specification:** The tests, analytical methods, and acceptance criteria to which an API or other components, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
m. **Stability:** The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
n. **Sterility:** The absence of viable microorganisms.
o. **Workflow management system:** Technology comprised of hardware and software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.
p. **Verify:** To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.

6. Related Policies, Documents, References

a. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
b. United States Pharmacopeial Convention, Inc. <788> Particulate Matter in Injections. Current version.
c. United States Pharmacopeial Convention, Inc. <789> Subvisible Particulate Matter in Ophthalmic Solutions. Current version.
d. United States Pharmacopeial Convention, Inc. <1163> Quality Assurance in Pharmaceutical Compounding. Current version.
e. United States Pharmacopeial Convention, Inc. <1207> Packaging Integrity Evaluation – Sterile Products. Current version.
f. United States Pharmacopeial Convention, Inc. <1211> Sterility Assurance. Current version.
g. United States Pharmacopeial Convention, Inc. <1225> Validation of Compendial Procedures. Current version.

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7. SOP Major Change and Review Summary

Date	Section	Description of Change
12/03/2024	All	SOP Implementation
12/31/2024	All	Annual Review

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Section Name: Personnel Training & Evaluation	Policy Name: Sterile Compounding Personnel Training and Competency
Policy Number/ Version: P-0204.1	Last Revision/Review Date: 12/31/2024

1. Overview and Scope

a. This policy serves as the written Sterile Compounding Training and Evaluation Program for Source Pharmacy and describes the procedures for training and evaluating sterile practice knowledge and competencies of personnel involved in or having direct oversight of compounded sterile preparations (CSPs). Refer to **Form F-0210** for a summary of the Sterile Training and Competency Program.

b. The Sterile Compounding Training & Competency Program equips compounding personnel with didactic knowledge and practical training in the foundational principles of sterile compounding. Competency evaluations validate proficiency in the required skills necessary to perform related job functions and maintain the quality of the sterile environment. The Program consists of initial and ongoing training and evaluation in the following areas:

   i. **Sterile Compounding Core Competencies and Principles Knowledge-** demonstrates Compounding Personnel possess the knowledge of and proficiency in the skills necessary to perform sterile manipulations and achieve and maintain appropriate environmental conditions.

   ii. **Hand Hygiene and Garbing Competency (including Gloved Fingertip and Thumb Sampling)-** ensures Compounding Personnel can safely and effectively complete hand hygiene, garbing, and donning of gloves without touch contamination.

   iii. **Aseptic Manipulation Competency (including Media Fill)-** validates Compounding Personnel aseptic technique and related manipulations within an ISO 5 compounding environment.

c. The USP Expert Committee has recognized an effective sterile compounding practice involves personnel, vendors, and other visitors that are not directly compounding or performing compounding related activities. Consequently, training and evaluation requirements are defined based on role and potential risk for contaminating the sterile compounding areas.

   i. **Compounding Personnel–** individuals performing or directly overseeing compounding activities as well as the Designated Person(s).

   ii. **Inventory and Cleaning Personnel–** individuals performing restocking or cleaning and disinfecting activities and that do not directly or indirectly participate in compounding CSPs.

   iii. **In-Process & Final Verification Personnel–** typically pharmacists, who do not participate in compounding or the oversight of compounding activities.

   iv. **Other Personnel & Visitors–** individuals who have a need to enter compounding areas (under supervision) but do not participate in or support the compounding activities in any way.

d. When performing aseptic manipulations according to the related USP standards and training and qualification requirements, personnel compounding the following types of sterile compounds are exempt from this policy:

   i. Licensed allergenic extracts.

   ii. Blood-derived and other biological materials.

   iii. Sterile radiopharmaceuticals.

   iv. Immediate-use compounds.

   v. Sterile drug preparation per approved manufacturer's labeling.

   vi. Proprietary bag and vial systems docked and activated for immediate administration to a single patient.

   vii. This policy applies to compounding only non-hazardous CSPs.

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2. Policy

a. Compounding and supporting personnel successfully complete training and demonstrate knowledge of and proficiency in all skills and competencies necessary to maintain the quality of the compounding environment and perform job-related functions before compounding CSPs, supervising, or performing support-related activities independently and complete refresher training and requalification as outlined below;

Personnel Function	**Training & Competency in Maintaining Quality of Compounding Environment**	**Training & Competency in Sterile Compounding Principles & Practices**	**Hand Hygiene & Garbing Competency*** ***(Including GFT)***	**Aseptic Manipulation Competency*** ***(Including Media Fill, Post-GFT, and Surface Sample)***
Compounding Personnel: Personnel compounding or with direct oversight of compounding personnel & activities				
Compounder	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 6 months	Initially & Every 6 months
Designated Person(s)	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months
Assigned Trainer(s)	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months
Personnel with Direct Oversight of Compounding Personnel	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months
Supporting Personnel: Personnel performing supporting roles that do not involve direct involvement in or oversight of compounding personnel or compounding activities				
Persons performing In-Process Checks & Final Verifications	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months
Personnel Cleaning or Restock Compounding Area(s)	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months
Personnel performing Immediate Use Compounding	Initially & Every 12 months	Initially & Every 12 months	Initially & Every 12 months *Excluding GFT; performed in non-classified area	Initially & Every 12 months *Excluding MF, GFT & SS; performed in non-classified area
Other Personnel & Visitors (e.g., maintenance personnel, certifiers, contractors, inspectors, surveyors, students)	Not Required Must be supervised by DP(s) at all times and comply with Hand Hygiene, Garbing, Materials Movement, & Conduct policies			

b. Knowledge and Core Skill Competencies:

i. Compounding personnel involved in or having direct oversight of compounding CSPs ("Compounding Personnel") as well as the Designated Person(s) and Assigned Trainer(s) (AT)

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complete training and evaluation in core competencies, skills, and sterile practice principles including, but not limited to:

a. Sterile core competencies and skills in maintaining the quality of the sterile compounding environment including, but not limited to:
    i. Hand hygiene.
    ii. Garbing.
    iii. Cleaning and disinfection.
    iv. Calculations, measuring, and mixing.
    v. Aseptic technique.
    vi. Achieving and/or maintaining sterility (and apyrogenicity if compounding with non-sterile components).
    vii. Use of equipment.
    viii. Documentation of the compounding process (e.g., master formulation and compounding records).
    ix. Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area.
    x. Proper use of primary engineering controls (PECs).
    xi. Principles of movement of materials and personnel within the compounding area.
b. Sterile compounding principles and practices including, but not limited to:
    i. USP <797> Pharmaceutical Compounding – Sterile Preparations, other applicable standards, and relevant literature.
    ii. Source Pharmacy Standard Operating Procedures related to sterile compounding and related job duties.
    iii. Beyond use dating, packaging, storage, and labeling of CSPs.
    iv. Quality assurance and quality control procedures (including release inspections and tests if applicable).
    v. Use of IV Workflow System(s) and other resources and database.
    vi. Understanding and use of Safety Data Sheets (SDS).
    vii. Reading and understanding Certificate of Analysis (COA).

ii. Personnel in supporting roles complete training and evaluation in job-related core competencies, skills, and sterile principles and practices including, at a minimum:

Core Skill	Restocking Personnel	Cleaning Personnel	CSP Verification Personnel
Hand Hygiene and Garbing	X	X	X
Cleaning/ Disinfecting		X	
Principles of Materials Movement & Conduct within Controlled Areas	X	X	X
CSP Quality Assurance/Quality Control Procedures			X

iii. The Designated Person(s) assigns the role of Assigned Trainer (AT) to personnel who are responsible for or assist in training and evaluating competency of compounding personnel.

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iv. Core skills, competencies, and knowledge are assessed with hands-on demonstration of skill under direct observation by a DP or AT and sterile principles knowledge is assessed via written or electronic examination.

v. Successful or "passing" results for the Sterile Core Competencies and Knowledge Assessment are:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 12 Months
Competency-based checklist with 100% proficiency	USP <797> & Sterile Principles Knowledge Exam	≥ 80% cumulative score	≥ 80% cumulative score

c. Hand Hygiene and Garbing Competency:

i. Hand hygiene and garbing competencies are assessed with hands-on demonstration of skill under direct observation by a DP or AT and validated via the Gloved Fingertip and Thumb Sampling Assessment.

a. **Initial Gloved Fingertip and Thumb Sampling Assessment (GFS):** successfully completed three separate times prior to compounding independently; each GFS is conducted separately after completing the hand hygiene and garbing procedure.

b. **Ongoing Gloved Fingertip and Thumb Sampling Assessments:** successfully completed at least once every 6 months for Compounding Personnel requalification.

ii. Successful or "passing" results for the Hand Hygiene and Garbing Competency are:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 6 Months
Competency-based checklist with 100% proficiency	Gloved fingertip assessment	3 separate assessments • 6 total plates (1 plate per hand per assessment) 7-day incubation with zero (0) CFUs	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with zero (0) CFUs

iii. Microbial identification of cultured CFU(s) is not required for Gloved Fingertip and Thumb Sampling.

d. Aseptic Manipulation Competency:

i. The Aseptic Manipulation Competency is administered, observed, and documented by the DP or AT and consists of four components:

a. Media Fill Testing
b. Direct visual observation of aseptic technique and manipulations
c. Gloved Fingertip and Thumb Sampling of both hands after the media fill test
d. Surface Sampling of the Direct Compounding Area (DCA) after the media fill test

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ii. The Media Fill Test(s) simulates the most difficult and challenging compounding procedure(s), compounding environments, and processing condition(s). Refer to Appendix Two for a summary of Media Fill Tests used.

iii. Successful or "passing" results for the Initial and Ongoing Aseptic Manipulations Competency is as follows:

Observation	Validation	Initial Prior to Compounding Independently	Ongoing Every 6 Months
Competency-based checklist with 100% proficiency	Media Fill	1 assessment 14-day incubation with no growth or turbidity	1 assessment 14-day incubation with no growth or turbidity
	Post Media Fill Gloved fingertip assessment	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)	1 assessment • 2 total plates (1 plate per hand) 7-day incubation with ≤ 3 CFU combined (total)
	Surface sample	1 sample of direct compounding area (DCA) 7-day incubation with ≤ 3 CFU	1 sample of DCA 7-day incubation with ≤ 3 CFU

iv. If any portion of the Hand Hygiene and Garbing or Aseptic Manipulations Competency does not meet the minimum passing result, the respective competency is repeated in its entirety. Failures in other Core Competencies are repeated individually. Documentation of the failure, corrective actions, and the repeated competency results is retained and readily accessible.

v. In the event of repeated, sequential failures of Core Competencies: Hand Hygiene and Garbing Competency and/or Aseptic Manipulations Competency, corrective action plans are implemented that are consistent with Board of Pharmacy requirements and under the review and discretion of the DP. Patterns of competency failures over time are assessed on a case-by-case basis.

	Initial	Ongoing
1st Failure	• Coaching and retraining • Repeat failed competency *STATUS: Independent compounding not allowed until all competencies are successfully completed.*	• Coaching • Repeat failed competency *STATUS: Allowed to continue with compounding duties while results pending.*

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	Initial	Ongoing
2nd Failure	• Extensive skills and foundation knowledge retraining • Repeat failed competency *STATUS: Independent compounding is not allowed. If passed, consider increased competency assessment requirements (e.g. every month for 3 months).*	• Skills and foundational knowledge retraining • Repeat failed competency *STATUS: Independent compounding is not allowed; reassign to non-compounding duties while results pending.*
3rd Failure	• Reassign to non-compounding role; consider referral to HR. *STATUS: Reassigned outside of sterile compounding practice.*	• Reassign to non-compounding role, consider referral to HR. *STATUS: Future sterile training requires completion of initial training and competency requirements and increased competency assessments.*

vi. Other personnel or visitors who do not undergo training and evaluation in core competencies, skills, or knowledge required to maintain the quality of the sterile compounding environment, are required to, at a minimum:
   a. Adhere to all aspects of the Hand Hygiene and Garbing policy **(P-0301)** and procedure.
   b. Comply with proper materials movement and cleaning procedures.
   c. Only enter a controlled compounding area under direct supervision of the DP or designee
   d. Minimize movement within the controlled areas and contact with any surfaces

vii. Compounding personnel performing specialized roles and responsibilities within the sterile practice complete initial training and knowledge assessments before performing these tasks independently. Training and evaluation are administered and documented by the DP or a qualified 3rd party. Ongoing reeducation and assessment in these specialized skills is conducted at least every 12 months. Training and evaluation are provided for the following specialized sterile practice roles and responsibilities:
   a. Environmental Monitoring Specialist – Total Particle Counts, Viable Airborne Sampling, and Surface Sampling.
   b. Media Incubation and Reading of Solid and Liquid Media Results.
   c. Sterile Equipment Validation (e.g. autoclave, dry heat oven, lyophilized, etc.).
   d. CSP Sterility and Endotoxin Testing.
   e. Glassware and Compounding Equipment Sterilization and Depyrogenation.
   f. Nonsterile-to-Sterile Compounding Sterilization Techniques.

3. Roles & Responsibilities

a. The Designated Person(s) (DP):

i. Oversees the Sterile Training and Evaluation Program for Compounding Personnel and supporting personnel involved in or supporting compounding activities.

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ii. Reviews competency results, evaluation and determination of corrective actions, and monitors for longer-term trends with Compounding Personnel Competency performance.
iii. Ensures non-compounding personnel and visitors who enter the sterile compounding area and/or handle CSPs understand the expectations appropriate to their role or are directly observed to ensure compliance and minimize impact to the quality of the sterile environment.
iv. May designate and qualify an Assigned Trainer(s) (AT) to assist with the training, evaluation, and competency administration process.
v. May define additional training and competency evaluation requirements for compounding personnel performing specialized roles or responsibilities.

b. Assigned Trainer(s) (AT):

i. Responsible and accountable for directly providing the training, observation, and/or evaluation of personnel performing compounding related activities.

c. Compounding personnel and supporting roles:

i. Successfully complete assigned training and demonstrate proficiency via competency assessment on a timely basis and before the evaluation activities are past due.
ii. Uphold sterile practice and quality standards to help ensure the quality of the sterile compounding area.

4. Procedures

a. Sterile Compounding Knowledge, Skills and Core Competency Assessment

i. DP or AT directly observes Compounding Personnel performing the Core Competencies and Skills **(refer to Sections 2.b.i. and 2.b.ii.)** and records the completion in Simplifi 797 and the assessment on the appropriate written competency form.
ii. Core competency evaluation can be completed in a single or multiple observed sessions. If the process is completed in separate sessions, documentation reflects the date, time, and initials of the DP or AT performing and evaluating the specific competencies.
iii. Competencies for hand hygiene, garbing, and aseptic technique can be conducted concurrently with the respective competency assessment. Observations and evaluations of each competency are clearly documented on the respective competency form.

b. Documentation of the Hand Hygiene and Garbing and Aseptic Manipulation Competencies includes, at a minimum:

i. Name of person evaluated.
ii. Evaluation date and time.
iii. Media and component manufacturer, lot, and expiration date.
iv. Incubation temperatures.
v. Dates of Incubation.
vi. Competency results.
vii. Name of competency observer and individual(s) reading and documenting results.
viii. Corrective actions (if needed).

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c. Garbing Competency and Gloved Fingertip and Thumb Sampling Assessment Procedure

i. Remove sampling plates (or alternative sampling device) from refrigerator in manufacturer's overwrap and check expiration dates; do not use expired media.

ii. Collect other supplies needed black, fine tipped permanent marker and clear tape or wax film to seal sampling device, disinfect with sIPA 70%, and move supplies to controlled environment adhering to material transfer standard operating procedures **(P-0801)**.

iii. Allow sampling plates to come to room temperature just prior to sampling.

iv. Enter media lot numbers, expiration dates, and manufacturer on Personnel Sampling Log **(F-1803)**.

v. DP or AT labels the base (i.e. agar side) of the sampling plates legibly around the outer edge (or permanently affixed lid on slide). Label each sample plate with sample type (e.g. "GFS"), hand (e.g., "L" -left or "R" - right), sample number (e.g., 1, 2, or 3) for initial competency, date, and initials of individual.

vi. Complete hand hygiene and garbing under direct observation. See **(P-0301) Hand Hygiene and Garbing.**

d. GFS – LAFW:

i. Don sterile gloves but do NOT apply sIPA 70% to gloved hands.

ii. DP or AT sanitizes sterile gloves with sIPA 70%, removes the lid of a labeled sampling plate, and holds vertically.

iii. Compounding personnel gently rolls the pad of each finger, one at a time, in an arch across the top of the agar surface ensuring not to overlap fingerprints. A thumb print is then gently placed in the middle of the plate.

iv. The lid is immediately replaced, and the sample is set to the side.

v. Repeat sampling process for the second hand; ensure the correctly labeled plate is used.

vi. Immediately, after both hands have been sampled and without touching any surfaces, complete the garb doffing process.

vii. During the Initial GFT competency assessment, repeat the entire process two more times.

viii. After all samples are collected, seal plates with wax or tape to ensure the lid is not dislodged during transit, incubation, or results inspection.

e. Aseptic Manipulation Competency Procedure (including Media Fill and Post Media Fill Gloved Fingertip and Surface Sampling)

i. Collect supplies needed for the media fill testing, post media fill GFS (2 plates per media fill test), and surface sampling (1 plate per media fill test) Needed supplies include, but are not limited to: media fill components such as soybean casien bags, vials, sterile powder for reconstitution; compounding supplies such as empty EVA or PVC bags; transfer sets, needles, adaptors, syringes, sterilizing filter(s) or other supplies needed for non-sterile-to-sterile media fill; sample plates, black fine tipped permanent marker, clear tape or wax film to seal sampling device.

ii. When more than one media fill test is to be completed, ensure all necessary media, supplies, and sampling plates for each media fill are collected and organized prior to initiating assessment.

iii. Check all growth media components for expiration date. Do not use expired media. Allow sampling plates to come to room temperature just prior to sampling.

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iv. Inspect all sterile media fill components for cracks, leaks, or other potential factors that may have compromised product's sterility. Do not use media suspected of contamination or sterile container defects.
v. Disinfect all media and supplies with sIPA 70%, and move supplies to controlled environment.
vi. Enter media lot numbers, expiration dates, and manufacturers on the written Media Fill competency form.
vii. When more than one media fill test is to be completed, record each media fill on a separate competency form.
viii. DP or AT labels the base (i.e. agar side) of the sampling plates legibly around the outer edge (or permanently affixed lid on slide) and the final dosage unit(s) for the media fill test. Label each sample with sample type (e.g. "MF", "PMF-GFS", or "SS"), hand (e.g., "L" -left or "R" - right), date, and initials of individual.
ix. Stage all media and supplies within reach of Primary Engineering Control (PEC).
x. Disinfect gloved hands and all components with sIPA 70% prior to being moved into the ISO Class 5 area of the PEC.
xi. Perform media fill under direct observation per procedure **F-0201**.
xii. sIPA 70% is used throughout the media fill process to sanitize sterile gloves, critical sites, and the direct compounding area; however, do not apply sIPA 70% to gloved hands or the DCA after the final step of the media fill procedure.
xiii. Nonsterile solutions are reconstituted and manipulated in a manner that simulates typical nonsterile-to-sterile compounding activities.
    a. Commercially available nonsterile soybean–casein digest powder is dissolved in non-bacteriostatic water creating a 3% nonsterile solution as part of the procedure.
    b. At least 1 container of non-sterile broth is compounded and incubated as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation.
    c. Retain sterilizing filter for bubble point testing and filter packaging displaying the lot and expiration of the filter to record on and/or affix to the media fill records.
xiv. Immediately following the final step of the media fill procedure and before sIPA is applied to gloved hands or the DCA:
    a. DP or AT performs the post media fill GFS (PMF-GFS) and DCA surface sample inside the ISO 5 PEC. GFS sampling is performed for both hands with one plate per hand. Refer to the GFS sampling procedures above in 4.1.
xv. Perform a bubble point test on the sterilizing filter and record both the expected and achieved PSI on the Media Fill form.
    a. If the sterilizing filter does not pass the bubble point test, the media is considered non-sterile and is re-sterilized inside an ISO 5 PEC with a new sterilizing filter. The new filter undergoes bubble point testing and PSI results are recorded.
xvi. Remove all other trash from the PEC and clean and disinfect PEC prior to commencing compounding.
xvii. Remove and replace sterile gloves immediately without touching any other surfaces; gloves are contaminated with growth medium. Repeat hand hygiene and garbing prior to returning to compounding activities.

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f. Selection, Incubation, & Interpretation of Media

i. Media Selection:

a. Select a general microbial growth agar (plate) supporting both bacterial and fungal growth, such as trypticase soy agar (TSA), for gloved fingertip and surface sampling. Growth medium contains additives that neutralize residual cleaning solutions, such as lecithin and polysorbate 80.

b. For media fill procedures, replace all CSP components with soybean–casein digest media components.

c. Obtain a Certificate of Analysis (COA) from the growth media supplier or manufacturer. The DP reviews and retains the COA to ensure the culture media supports growth of microorganisms (as defined in Table 1 of USP <71>). Store media per manufacturer instructions and media is used in accordance with manufacturer instructions and before the expiration date of the media.

g. Media Incubation & Interpretation:

i. Locate calibrated incubators monitored by NIST certified temperature gauge outside of the sterile compounding area. A minimum of two incubators are available:

a. Incubator 1: calibrated and maintained at 20° to 25°C.

b. Incubator 2: calibrated and maintained at 30° to 35°C.

ii. Invert gloved fingertip and surface sample agar plates during incubation to ensure moisture condensation does not collect and fall onto the agar surface which can contaminate and/or invalidate the results.

iii. Incubation temperatures and timeframes:

Competency	Media	1st Incubation	2nd Incubation	Total Incubation Timeframe
Gloved fingertip and surface samples	TSA agar plate, paddle or slide with polysorbate 80 & lecithin (neutralizers)	≥ 48 hours at 30°C - 35°C (86-95°F)	≥ 5 Days at 20°C - 25°C (68-77°F)	≥ 7 Days
Media fill test final dose unit(s)	Soybean casein digest (all components)	7 Days at 20°C - 25°C (68-77°F)	7 Days at 30°C - 35°C (86-95°F)	14 Days

iv. Only the DP is qualified to manage, read, and interpret media places or moves media into and out of incubators.

v. Record date, time, incubator temperature, and person(s) moving media into and between incubators on competency form(s).

vi. Read and record CFU counts per sampling plate and examine media fill bags/units for visible changes daily or, at a minimum, when media are moved from the first to the second incubator. Record interim results on competency form(s).

vii. Read and record CFU counts per sampling plate at the conclusion of the full incubation; total CFU counts from all plates to determine the final CFU count results. Record results on the competency form(s).

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viii. Examine the media fill bag/units for any visible turbidity or changes indicating growth at the conclusion of the full incubation against a white and black background in a well-lit area, record either a pass or failed result on the Media Fill form.

ix. Complete the necessary chain of custody forms and prepare, package, and ship/deliver media per the specifications provided by the 3rd party laboratory.

x. The DP reviews the Certificate of Analysis and results report provided by the laboratory and takes appropriate measures to either complete and store the documentation for a successfully completed assessment or evaluate, recommend, and document next steps for failed media results.

h. **Corrective Action for Competency Failure**

i. Any personnel failing to demonstrate competency during a foundational knowledge exam or hands-on skills assessment is coached and reinstructed on the applicable policy, technique(s), and foundational knowledge related to the skill; and subsequently re-evaluated by the DP or AT.

ii. Evaluation and corrective action for observed competencies is documented within the competency form **(F-0601)**. Corrective action records are used for long-term assessment of personnel competency and potential contributing factors to maintaining a state of microbial control within the sterile compounding environment.

i. Extended Absence or Frequency of Compounding

i. If personnel are not actively engaged in CSP activities for 6 months or are on extended leave during the time their observed competencies are due, initial training and competency is assigned upon their return.

ii. Initial training and competency assessments are completed before re-entry to CSP activities and compounding independently.

j. **Ongoing Training**

i. The DP is responsible for assessing the training needs of personnel and the appropriate method for communication and delivery as new or updated equipment, components, recipes, or procedures are introduced.

ii. Ongoing training may be communicated in a staff meeting, email, and/or formal program.

iii. Ongoing training will be documented in the Training Roster **F-0211**. All supporting documentation including but not limited to: learning objectives, training materials, or post education testing will be attached to the Training Roster **F-0211**.

k. **Monitoring of Compounding Activities**

i. The DP conducts quarterly tracer observations of CSP personnel and processes.

ii. If deficient practices are observed, the DP discusses the following with the personnel:

a. Identify the issue(s) observed.

b. Review and reinstruct on the expected practice.

c. Confirm understanding with a return demonstration or teach back method.

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5. Definitions

a. **Assigned Trainer (AT):** One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation and/or evaluation of personnel for the preparations of CSPs.
b. **CSP:** compounded sterile preparation
c. **Designated Person (DP):** One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.
d. **Direct Compounding Area (DCA):** A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
e. **Laminar airflow workbench (LAFW):** An LAFW is a device that provides an ISO Class 5 or better environment for sterile compounding. The LAFW provides either horizontal or vertical unidirectional HEPA-filtered airflow.
f. **Media-fill test:** A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
g. **Primary Engineering Control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding. (Ex: LAFW, BSC, RABS, CAI, CACI)
h. **sIPA:** sterile 70% isopropyl alcohol.
i. **Secondary Engineering Control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
j. **Segregated Compounding Area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.

6. Related Policies, Documents, References

a. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
b. United States Pharmacopeial Convention, Inc. <71> Sterility Tests, Culture Media, and Incubation Temperatures, Growth Promotion Test of Aerobes, Anaerobes, and Fungi. current version.

7. SOP Major Change and Review Summary

Date	Section	Description of Change
12/03/2024	All	SOP Implementation
12/31/2024	All	Annual Review

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Section Name: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants	Policy Name: Daily Cleaning and Disinfecting Sterile Compounding Areas
Policy Number/ Version: P-0701.1	Last Revision/Review Date: 12/31/2024

1. Overview and Scope

a. This policy describes the procedures for daily cleaning and disinfecting compounding areas where Compounded Preparations (CSP) are prepared within Source Pharmacy.
b. Surfaces in classified areas and segregated compounding areas are potential sources of microbial contamination. In order to reduce the risk of contact contamination, surfaces within classified areas used to prepare Category 1, and Category 2, are cleaned, disinfected, and have sporicidal disinfectants applied according to the processes and frequencies described in this procedure.
   i. **Cleaning** involves removing organic and inorganic materials (e.g., dirt, debris, microbes, and residual drugs or chemicals) form surfaces with the use of a cleaning agent and manual or mechanical action.
   ii. **Disinfecting** involves using a chemical or physical agent on surfaces to destroy microorganisms including fungi, viruses, and bacteria.
   iii. **Sporicidal disinfectants** are a chemical or physical agents that destroys all vegetative microorganisms including bacterial and fungal spores while applied at a sufficient concentration and for a specified "wet" contact time.
c. Sterile 70% isopropyl alcohol (sIPA) is a staple in day-to-day compounding activities and plays a critical role in sanitizing and reducing the bioburden on gloved hands, surfaces, and materials through both chemical application and physical wiping. sIPA, however, is not a cleaning or disinfecting agent. While it does have some disinfectant properties, it does not possess the broad-spectrum coverage of cleaning, disinfecting, or sporicidal agents and requires a lengthy (and impractical) contact time to truly convey bactericidal or fungicidal activity.

2. Policy

a. Cleaning and disinfecting of all surfaces inside compounding areas, including sinks, as well as the application of a sporicidal disinfectant occur on a regular basis and at a minimum frequency as specified in USP <797> Pharmaceutical Compounding – Sterile Preparations 2022 and according to this policy **(see Section 4a)**.
b. Surfaces in compounding areas are cleaned daily prior to being disinfected with an EPA-registered (or equivalent outside of the US) agent. An EPA-registered (or equivalent) one-step disinfectant cleaner is an appropriate alternative that allows for both processes to occur in one step.
c. Sporicidal disinfecting agents are EPA-registered (or equivalent outside of the US) and allow for cleaning, disinfecting, and sporicidal activity concurrently in a single step.
d. Manufacturer's directions or published data for the minimum wet contact time is followed for each of the cleaning, disinfecting, and sporicidal agents used to ensure the agents have full microbial destroying action.
e. If compounding (and cleaning) is not performed each day, cleaning and disinfecting is completed before reinitiating compounding.
f. Cleaning and sanitizing are repeated when spills occur and when surfaces are visibly soiled.
g. All personnel involved in cleaning and disinfecting of classified compounding and segregated compounding areas receive training and demonstrate competency in Hand Hygiene and Garbing **(P-0301)** initially and at least annually. Refresher training is provided as needed and when changes in procedures or agents occur.

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h. All cleaning and disinfecting activities are performed by appropriately garbed personnel using facility-approved agents and procedures including frequency, method, and location of cleaning activity.
i. Sterile cleaning agents are used to clean the interior of, and all equipment housed inside of PECs. Sterile cleaning agents are also used to clean SECs.
j. Cleaning agents and supplies used in PECs and SECs are assigned an expiration (or "in-use") date once opened or prepared; expiration dates are clearly and permanently written on the bottle, container, or wrapping of the supply and do not exceed manufacturer expiration dates or recommended "in-use" dates.

Cleaning Agent or Supply	Location Used	Expiration Date* (from initial puncture use, or preparation)
Ready-to-Use (RTU) STERILE Cleaning, Disinfecting, and Sporicidal Agents	Interior/Exterior PECs and All surfaces in SEC	30 Days
STERILE Premoistened or Low-Lint Dry Wipes	Inside PECs	30 Days unless wipes appear dry

***Consult the manufacturer for dates for specified products in use at your facility or define a more conservative expiration date.**

k. Safety Data Sheets (SDSs) are retained for all cleaning supplies, included in training of cleaning personnel, and are readily retrievable by all compounding staff members.
l. Since cleaning solutions are irritants and can damage the skin and eyes, safety glasses must be worn during cleaning of ceiling and walls; during mixing of cleaning agents and on other occasions when there is an increased likelihood of splashing or dripping of solution.
m. Compounding equipment (i.e. automated compounders, devices or pumps) placed into ISO Class 5 PECs are subject to the same cleaning requirements as the LAFW itself. These devices must be moved during daily cleaning so that the surface underneath may be cleaned and disinfected.

3. Roles & Responsibilities

a. **The Designated Person(s) (DP):**
   i. Ensures cleaning staff receives appropriate training and maintains current cleaning and related competencies.
   ii. Oversees selection of appropriate EPA-registered cleaning, disinfecting, and sporical agents and ensures staff understands and adheres to appropriate dwell times for each agent.
   iii. Ensures the organization or facility maintains a current SDS for each cleaning agent in a readily retrievable format and location and ensures cleaning personnel understand how to access and use the SDS in case of a spill or accident.
   iv. Determines appropriate remedial cleaning requirements for ad hoc and out-of-specification occurrences up to and including a triple clean of effected compounding areas including the following circumstances:
      a. Actionable environmental findings from total particle counts, viable air sampling, or surface sampling results and/or trends.
      b. Scheduled and unscheduled power and/or airflow disruptions directly impacting sterile compounding area(s).

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c. Certification of sterile compounding area(s).
d. New or major construction or maintenance work performed within or adjacent to the sterile compounding area(s).

b. Compounding personnel:

i. Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting.
ii. Adhere to all cleaning procedures including cleaning agent selection, frequency, method, and sequence of cleaning activities (i.e., cleanest to dirtiest).
iii. Ensure appropriate use of sterile 70% IPA before, during, and after the compounding process.
iv. Complete timely documentation of all cleaning activities performed.

4. Procedures

a. Frequency of Cleaning, Disinfection, and Application of Sporicidal Disinfectants – Adapted from USP <797> 2022 Table 8.

Cleaning and Disinfecting		
	Frequency	**Who**
Inside PECs – including all surfaces, direct compounding area and work tray, and equipment used inside the PEC	Daily on days when compounding occurs and when surface contamination is known or suspected	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Work Surfaces Outside of PEC	Daily on days when compounding occurs - all "high touch" surfaces daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Floors	Daily on days when compounding occurs	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Sinks	Daily on days when compounding occurs	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency

i. Cleaning activities occur from cleanest to dirtiest areas. When performing cleaning, wipe from top to bottom in overlapping strokes so that the surface is thoroughly wetted but not dripping. Allow the cleaning agent PeridoxRTU (germicidal detergent and sporicidal agent) to dwell for 3 minutes and to dry on its own and disinfecting agent (sterile 70% IPA) to dry on its

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own. Do not wipe off or dry the surface since that will reduce the dwell time and render the agent less effective.

a. To minimize odor, squeeze PeridoxRTU (do not use spray triggers) directly onto wipes and/or mop head to reduce odor. Cleaning agents must be applied to the applicator, not to the target surface.
b. Apply only the amount of PeridoxRTU needed to clean the immediate area, while ensuring the applicator is sufficiently wet to facilitate achievement of dwell time per product label instructions.
c. If excess PeridoxRTU is unintentionally applied, use a dry wipe, suitable for the controlled environment, to absorb the excess.

ii. Cleaning and disinfecting are performed as separate steps, cleaning is performed prior to disinfecting.

iii. After the application of the cleaning agent, the agent (PeridoxRTU) is allowed to dwell, or maintain a wet contact time, for the minimum duration of 3 minutes as specified by the manufacturer and published data to ensure full bactericidal, fungicidal, virucidal, and/or sporicidal action.

iv. Daily cleaning and disinfecting occur on days when compounding occurs. If compounding does not occur for more than 24 hours (e.g., over a weekend or holiday):

a. Clean and disinfect the sink(s) before initiating hand hygiene and garbing
b. Complete daily cleaning and disinfecting prior to the start of compounding on the day compounding resumes.

v. Cleaning and disinfection of the inside of a PEC and any equipment housed and used inside a PEC occurs prior to and at the conclusion of daily and/or shift compounding.

b. Cleaning, and Applying Disinfectants in the PEC

i. Inspect the inside of the PEC for any spills or puddles of crystallized compounding components. If needed, remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.

ii. **For cleaning and disinfecting:** Use a sterile low-lint wiper and apply PeridoxRTU (a sterile cleaning agent) followed by sterile IPA 70% (a sterile disinfecting agent).

iii. Begin cleaning activity within the LAFW environment moving outward working from top to bottom and inner to outer surface. Note: Apply only the amount of PeridoxRTU needed to clean the immediate area, while ensuring the applicator is sufficiently wet to facilitate achievement of dwell time (3 minutes). Do not use spray triggers at any time on the HEPA filter with any cleaning or disinfectant solution. Carefully clean the HEPA grills. Order of cleaning of surfaces inside any PEC is as follows:

a. Ceiling inside the PEC which contains the HEPA filters in vertical flows

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b. Back surface which contains the HEPA filters in horizontal flows being careful not to splash the HEPA filter while cleaning the diffuser or protective screen.
c. Sides (left and right) as well as IV bar and hangers
d. Anything on the deck (work surface of the PEC)
e. Deck itself

iv. Ensure the wet contact time (3 minutes) specified by the manufacturer is achieved. If necessary, reapply to maintain a properly wet surface in order to achieve desired results.

v. After the application of cleaning, disinfecting, agent inside PEC, apply sIPA 70% to equipment and all interior surfaces to remove residue.

vi. Allow the surface to dry completely before beginning compounding. If daily cleaning was performed the night before, at the start of each new workday, the LAFW must be wiped down with a wipe wetted with sterile 70% IPA **(see Section 4c)**.

c. Use of Sterile 70% IPA inside of a PEC

i. Do not spray cleaning solutions, including sIPA, inside of a PEC to avoid deteriorating the integrity of the HEPA filter. Wet a sterile low-lint wiper with sIPA 70% and apply directly with mechanical/manual action to the interior hood surfaces and equipment.
ii. Apply sIPA 70% to the horizontal work surface of each PEC and allow to dry before compounding:
    a. Immediately before initiating compounding or a new compounding process.
    b. At least every 30 minutes if the compounding process takes 30 minutes or less.
    c. After completing a compounding process if the process takes more than 30 minutes.

d. Other Cleaning Considerations

i. Clean high touch surfaces outside of PECs on a daily basis including but not limited to:

High Touch Surfaces*
• Horizontal work surfaces, tables, counters, or carts • Chair seats, arms, and backs • Keyboards/keypads, mouse, RF scanner, touch screen monitors or tablets • Telephones and other communication devices • Light switches, door handles or hands-free activator • Sink surfaces, drain, and faucet • Gowning bench and garb storage handles

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ii. Cleaning, and disinfecting does not take place while active compounding is occurring.

iii. Perform cleaning from cleaner to dirtier areas (e.g. ISO 5, ISO 7, and then ISO 8 areas) therefore, the of the primary engineering controls (ISO Class 5 area) is cleaned first followed by the ISO Class 7 buffer area followed by the ISO Class 8 ante-area then general pharmacy preparation area.

iv. For all sites, clean and disinfect as needed after spills and when surface contamination (e.g., splashes) is known or suspected.

v. Replace all garb after cleaning and prior to resuming compounding duties; repeat hand hygiene and replace sterile gloves before returning to compounding.

vi. Use appropriate respiratory support and eye protection when applying a sporicidal agent to surfaces within the compounding area, including the following cleaning tasks:
   a. Walls, ceilings, and floors.
   b. Surfaces outside of PECs.

e. Selection and Use of Cleaning Agents

i. Select and use cleaning and disinfecting agents with careful consideration of compatibilities, effectiveness, and user safety including, but not limited to, antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected.

ii. Use of ready-to-use and one-step disinfectant cleaner solutions is preferred over those requiring dilution or separate cleaning and disinfection steps.

iii. Clean and disinfect sterile cleaning agent containers prior to introduction into the ISO 5 environment **(P-0801)**.

iv. Sterile cleaning and disinfecting supplies (e.g., closed containers of sterile wipers, bottles of 70% sterile IPA) can be used for up to 30 days once opened. Permanently and legibly write or label the expiration date on all cleaning supplies. Date opened, expiration date, and individual's initials but be clearly notated.

v. Store opened packages of sterile wipes inside of the PEC; if removed from a PEC once opened, they are no longer considered sterile and can only be used in ISO Class 7 and 8 areas.

vi. Disinfect sterile cleaning solution bottles stored outside of a PEC prior to introduction and use inside of the PEC with sIPA 70% **(P-0801)**.

vii. Use sterile cleaning and disinfecting agents in all classified areas including PECs and SECs.

f. Selection and Use of Cleaning Supplies and Tools

i. Use only sterile cleaning supplies (pads, mop heads) and stainless-steel tools inside a PEC; clean and disinfect stainless steel tools prior to use (e.g., tool handles and holders).

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ii. Dedicated reusable cleaning tools (e.g. mop frames and handles) are to remain in specific classified areas.
   a. Dedicated mop frames are available in buffer and ante rooms and should never be removed. If removed following procedure **(P-0901)** for the introduction of equipment into the cleanroom.
   b. Dispose of elements of cleaning tools (pads, mop-heads) in a method that minimizes the chance of dispersing contaminants in the air.

iii. Cleaning and disinfecting supplies such as wipers, sponges, pads, and mop heads are made of low lint materials and are disposable.
   a. Disposable cleaning supplies are discarded after each use.
   b. Reusable cleaning tool components are made of cleanable materials that are nonporous (excluding wood) are cleaned and disinfected before and after each use.

iv. Clean compounding equipment used (e.g., mortar and pestle, cylinders, beakers, stir bars, etc.) as soon as possible after compounding is completed.

v. Use the dedicated sink located in the non-classified general pharmacy/lab area for cleaning compounding equipment and supplies.

g. Documentation of Cleaning

i. Document all cleaning, disinfecting, and application of sporicidal disinfectants electronically within Simplfi 797 or on form **(F-0702)** in the event of system downtime (see **P-1802**) after completion of the task by the personnel performing the work. Detailed cleaning records are retained and readily accessible.

5. Definitions

a. **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).
b. **Cleaning agent:** An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
c. **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).
d. **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
e. **IPA:** Isopropyl alcohol.
f. **Low-lint wiper:** A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.
g. **One-step disinfectant cleaner:** A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

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h. **Pass-through:** An enclosure with sealed doors on both sides that should be interlocked. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
i. **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
j. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
k. **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.
l. **Sporicidal disinfectant:** A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms
m. **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

6. Related Policies, Documents, References

a. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

7. SOP Major Change and Review Summary

Date	Section	Description of Change
12/03/2024	All	SOP Implementation
12/31/2024	All	Annual Review

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Section Name: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants	Policy Name: Monthly Cleaning and Disinfecting Sterile Compounding Areas
Policy Number/ Version: P-0702.1	Last Revision/Review Date: 12/31/2024

1. Overview and Scope

a. This policy describes the procedures for daily cleaning and disinfecting compounding areas where Compounded Preparations (CSP) are prepared within Source Pharmacy.
b. Surfaces in classified areas and segregated compounding areas are potential sources of microbial contamination. In order to reduce the risk of contact contamination, surfaces within classified areas used to prepare Category 1 and Category 2 are cleaned, disinfected, and have sporicidal disinfectants applied according to the processes and frequencies described in this procedure.
    a. **Cleaning** involves removing organic and inorganic materials (e.g., dirt, debris, microbes, and residual drugs or chemicals) form surfaces with the use of a cleaning agent and manual or mechanical action.
    b. **Disinfecting** involves using a chemical or physical agent on surfaces to destroy microorganisms including fungi, viruses, and bacteria.
    c. **Sporicidal disinfectants** are a chemical or physical agent that destroys all vegetative microorganisms including bacterial and fungal spores while applied at a sufficient concentration and for a specified "wet" contact time.
    d. **Sterile 70% isopropyl alcohol (sIPA)** is a staple in day-to-day compounding activities and plays a critical role in sanitizing and reducing the bioburden on gloved hands, surfaces, and materials through both chemical application and physical wiping. sIPA, however, is not a cleaning or disinfecting agent. While it does have some disinfectant properties, it does not possess the broad-spectrum coverage of cleaning, disinfecting, or sporicidal agents and requires a lengthy (and impractical) contact time to truly convey bactericidal or fungicidal activity.

2. Policy

a. Cleaning and disinfecting of all surfaces inside compounding areas, including sinks, as well as the application of a sporicidal disinfectant occur on a regular basis and at a minimum frequency as specified in *USP <797> Pharmaceutical Compounding – Sterile Preparations 2022* and according to this policy **(see Section 4a)**.
b. Surfaces in compounding areas are cleaned daily prior to being disinfected with an EPA-registered (or equivalent outside of the US) agent. An EPA-registered (or equivalent) one-step disinfectant cleaner is an appropriate alternative that allows for both processes to occur in one step.
c. Sporicidal disinfecting agents are EPA-registered (or equivalent outside of the US) and allow for cleaning, disinfecting, and sporicidal activity concurrently in a single step.
d. Manufacturer's directions or published data for the minimum wet contact time is followed for each of the cleaning, disinfecting, and sporicidal agents used to ensure the agents have full microbial destroying action.
e. If compounding (and cleaning) is not performed each day, cleaning and disinfecting is completed before reinitiating compounding.
f. Cleaning and sanitizing is repeated when spills occur and when surfaces are visibly soiled.
g. All personnel involved in cleaning and disinfecting of classified compounding and segregated compounding areas receive training and demonstrate competency in Hand Hygiene and Garbing **(P-0301)** initially and at least annually. Refresher training is provided as needed and when changes in procedures or agents occur.

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h. All cleaning and disinfecting activities are performed by appropriately garbed personnel using facility-approved agents and procedures including frequency, method, and location of cleaning activity.
i. Sterile cleaning agents are used to clean the interior of, and all equipment housed inside of PECs. Sterile cleaning agents are also used to clean SECs.
j. Cleaning agents and supplies used in PECs and SECs are assigned an expiration (or "in-use") date once opened or prepared; expiration dates are clearly and permanently written on the bottle, container, or wrapping of the supply and do not exceed manufacturer expiration dates or recommended "in-use" dates.

Cleaning Agent or Supply	Location Used	Expiration Date* (from initial puncture, use, or preparation)
Ready-to-Use (RTU) STERILE Cleaning, Disinfecting, and Sporicidal Agents	Inside PECs	30 Days
STERILE Premoistened or Low-Lint Dry Wipes	Inside PECs	30 Days unless wipes appear dry

k. Safety Data Sheets (SDSs) are retained for all cleaning supplies, included in training of cleaning personnel, and are readily retrievable by all compounding staff members.
l. Since cleaning solutions are irritants and can damage the skin and eyes, safety glasses must be worn during cleaning of ceiling and walls; during mixing of cleaning agents and on other occasions when there is an increased likelihood of splashing or dripping of solution.
m. Compounding equipment (i.e. automated compounders, devices or pumps) placed into ISO Class 5 PECs are subject to the same cleaning requirements as the LAFW, BSC, CACI or CAI itself. These devices must be moved during daily cleaning so that the surface underneath may be cleaned and disinfected.

3. Roles & Responsibilities

a. The Designated Person(s) (DP):

i. Ensures cleaning staff receives appropriate training and maintains current cleaning and related competencies.
ii. Oversees selection of appropriate EPA-registered cleaning, disinfecting, and sporical agents and ensures staff understands and adheres to appropriate dwell times for each agent.
iii. Ensures the organization or facility maintains a current SDS for each cleaning agent in a readily retrievable format and location and ensures cleaning personnel understand how to access and use the SDS in case of a spill or accident.
iv. Determines appropriate remedial cleaning requirements for ad hoc and out-of-specification occurrences up to and including a triple clean of effected compounding areas including the following circumstances:
    a. Actionable environmental findings from total particle counts, viable air sampling, or surface sampling results and/or trends.
    b. Scheduled and unscheduled power and/or airflow disruptions directly impacting sterile compounding area(s).
    c. Certification of sterile compounding area(s).

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d. New or major construction or maintenance work performed within or adjacent to the sterile compounding area(s).

b. Compounding personnel:

i. Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting **(P-0203)**.
ii. Adhere to all cleaning procedures including cleaning agent selection, frequency, method, and sequence of cleaning activities (i.e., cleanest to dirtiest).
iii. Ensure appropriate use of sterile 70% IPA before, during, and after the compounding process.
iv. Complete timely documentation of all cleaning activities performed.

4. Procedures

a. Frequency of Cleaning, Disinfection, and Application of Sporicidal Disinfectants – Adapted from *USP <797> 2022 Table 8.*

	Cleaning and Disinfecting		Applying Sporicidal Disinfectant	
	Frequency	**Who**	**Frequency**	**Who**
Inside PECs – including all surfaces, direct compounding area and work tray, and equipment used inside the PEC	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Work Surfaces Outside of PEC	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly – all surfaces including high touch and underneath of tables, chairs, and carts plus wheels.	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Floors	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any

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	Cleaning and Disinfecting		Applying Sporicidal Disinfectant	
	Frequency	Who	Frequency	Who
		trained personnel that have completed both training and competency		trained personnel that have completed both training and competency
Sinks	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Walls, Door(s), and Door Frame(s)	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Ceilings of Sterile Suite	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency

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	Cleaning and Disinfecting		**Applying Sporicidal Disinfectant**	
	Frequency	**Who**	**Frequency**	**Who**
Storage Shelves and Bins	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Equipment Outside of the PEC(s)	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency

i. Cleaning activities occur from cleanest to dirtiest areas. When performing cleaning, wipe from top to bottom in overlapping strokes so that the surface is thoroughly wetted but not dripping. Allow the cleaning agent PeridoxRTU (sporicidal agent) to dwell for 3 minutes and to dry on its own and disinfecting agent (sterile 70% IPA) to dry on its own. Do not wipe off or dry the surface since that will reduce the dwell time and render the agent less effective.
    a. To minimize odor, squeeze PeridoxRTU (do not use spray triggers) directly onto wipes and/or mop head to reduce odor. Cleaning agents must be applied to the applicator, not to the target surface.
    b. Apply only the amount of PeridoxRTU needed to clean the immediate area, while ensuring the applicator is sufficiently wet to facilitate achievement of dwell time per product label instructions.
    c. If excess PeridoxRTU is unintentionally applied, use a dry wipe, suitable for the controlled environment, to absorb the excess.

ii. Cleaning and disinfecting are performed as separate steps, cleaning is performed prior to disinfecting.

iii. After the application of a cleaning agent, or sporicidal disinfectant (PeridoxRTU), is allowed to dwell, or maintain a wet contact time, for the minimum duration of 3 minutes as specified by the manufacturer or published data to ensure full bactericidal, fungicidal, virucidal, and/or sporicidal action.

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iv. Daily cleaning and disinfecting occurs on days when compounding occurs. If compounding does not occur for more than 48 hours (e.g., over a long weekend or holiday):
   a. Clean and disinfect the sink(s) before initiating hand hygiene and garbing
   b. Complete daily cleaning and disinfecting prior to the start of compounding on the day compounding resumes.

v. Monthly cleaning and application of sporicidal disinfectant (PeridoxRTU) occurs approximately every 30 days, whenever possible, to ensure a regular and consistent cleaning schedule and is completed as one continuous process.

vi. Cleaning and disinfection of the inside of a PEC and any equipment housed and used inside a PEC occurs prior to and at the conclusion of daily and/or shift compounding.

b. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in the PEC

i. If needed, remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.

ii. **For cleaning and disinfecting:** Use a sterile low-lint wiper and apply PeridoxRTU (a sterile cleaning agent) followed by a sterile IPA 70% a (disinfecting agent).

iii. Begin cleaning activity within the LAFW environment moving outward working from top to bottom and inner to outer surface. **Note:** Apply only the amount of PeridoxRTU needed to clean the immediate area, while ensuring the applicator is sufficiently wet to facilitate achievement of dwell time (3 minutes). Do not use spray triggers at any time on the HEPA filter with any cleaning or disinfectant solution. Carefully clean the HEPA grills. Order of cleaning of surfaces inside any PEC is as follows:
   a. Ceiling inside the PEC which contains the HEPA filters in vertical flows.
   b. Back surface which contains the HEPA filters in horizontal flows being careful not to splash the HEPA filter while cleaning the diffuser or protective screen.
   c. Sides (left and right) as well as IV bar and hangers.
   d. Anything on the deck (work surface of the PEC).
   e. Deck itself.

iv. Ensure the wet contact/dwell time (3 minutes) specified by the manufacturer is achieved. If necessary, reapply to maintain a properly wet surface in order to achieve desired results.

v. After the application of cleaning, disinfecting, agent inside PEC, apply sIPA 70% to equipment and all interior surfaces to remove residue.

vi. Allow the surface to dry completely before beginning compounding. If daily cleaning was performed the night before, at the start of each new workday, the LAFW must be wiped down with a wipe wetted with sterile 70% IPA **(see Section 4i)**.

vii. **For application of a sporicidal disinfectant:** After cleaning and disinfecting, apply a sterile sporicidal disinfectant (PeridoxRTU) using a sterile low-lint wiper to all equipment, interior surfaces; since PeridoxRTU (the sporicidal disinfectant is an EPA-registered) is a one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required.

viii. Ensure the wet contact time of 3 minutes as specified by the manufacturer is achieved. If necessary, reapply to maintain a properly wet surface in order to achieve desired results.

ix. After the application of cleaning, disinfecting, and/or sporicidal agent inside PEC, apply sIPA 70% to equipment and all interior surfaces to remove residue.

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x. Allow the surface to dry completely before beginning compounding. If daily cleaning was performed the night before, at the start of each new workday, the LAFW must be wiped down with a wipe wetted with sterile 70% IPA **(see Section 4i)**.

c. Use of Sterile 70% IPA inside of a PEC

i. Do not spray cleaning solutions, including sIPA, inside of a PEC to avoid deteriorating the integrity of the HEPA filter. Wet a sterile low-lint wiper with the cleaning solution or sIPA and apply directly with mechanical/manual action to the interior hood surfaces and equipment.

ii. Apply sIPA 70% to the horizontal work surface of each PEC and allow to dry before compounding:
   a. Immediately before initiating compounding or a new compounding process.
   b. At least every 30 minutes if the compounding process takes 30 minutes or less.
   c. After completing a compounding process if the process takes more than 30 minutes.

d. Other Cleaning Considerations

i. Clean high touch surfaces outside of PECs on a daily basis and all other surfaces plus the high touch surfaces on a monthly frequency, including but not limited to:

High Touch Surfaces*	Other Surfaces
• Horizontal work surfaces, tables, counters, or carts • Chair seats, arms, and backs • Keyboards/keypads, mouse, RF scanner, touch screen monitors or tablets • Telephones and other communication devices • Light switches, door handles or hands-free activator • Sink surfaces, drain, and faucet • Gowning bench and garb storage handles	• Exterior of PECs • Legs, underside of horizontal surfaces, and feet/wheels of work surfaces, tables, counters, carts, chairs, or benches • Trash bins and hazardous waste disposal containers • Doorframes, window ledges, and other irregular surfaces

ii. Cleaning, disinfecting, and the application of a sporicidal agent does not take place while active compounding is occurring.

iii. Perform cleaning from cleaner to dirtier areas (e.g. ISO 5, ISO 7, and then ISO 8 areas) therefore, the of the primary engineering controls (ISO Class 5 area) is cleaned first followed by the ISO Class 7 buffer area followed by the ISO Class 8 ante-area then general pharmacy preparation area.

iv. For all sites, clean and disinfect as needed after spills and when surface contamination (e.g., splashes) is known or suspected.

v. Replace all garb after cleaning and prior to resuming compounding duties; repeat hand hygiene and replace sterile gloves before returning to compounding.

vi. Use appropriate respiratory support and eye protection when applying a sporicidal agent to surfaces within the compounding area, including the following cleaning tasks:

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a. Walls, ceilings, and floors.
b. Surfaces outside of PECs.

e. **Selection and Use of Cleaning Agents**
   i. Select and use cleaning and disinfecting agents with careful consideration of compatibilities, effectiveness, and user safety including, but not limited to, antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected.
   ii. Use of ready-to-use and one-step disinfectant cleaner solutions is preferred over those requiring dilution or separate cleaning and disinfection steps.
   iii. Clean and disinfect sterile cleaning agent containers prior to introduction into the ISO 5 environment **(P-0801)**.
   iv. Sterile cleaning and disinfecting supplies (e.g., closed containers of sterile wipers, bottles of 70% sterile IPA) can be used for up to 30 days once opened. Permanently and legibly write or label the expiration date on all cleaning supplies. Date opened, expiration date, and individual's initials but be clearly notated.
   v. Store opened packages of sterile wipes inside of the PEC; if removed from a PEC once opened, they are no longer considered sterile and can only be used in ISO Class 7 and 8 areas. Disinfect sterile cleaning solution bottles stored outside of a PEC prior to introduction and use inside of the PEC with sIPA 70% **(P-0801)**.
   vi. Use sterile cleaning and disinfecting agents in all classified areas including PECs and SECs.

f. **Selection and Use of Cleaning Supplies and Tools**
   i. Use only sterile cleaning supplies (pads, mop heads) and tools inside a PEC; clean and disinfect prior to use (e.g., tool handles and holders).
   ii. Dedicated reusable cleaning tools (e.g. mop frames and handles) are to remain in specific classified areas.
      a. Dedicated mop frames in buffer and ante rooms should never be removed. If removed following procedure **(P-0901)** for the introduction of equipment into the cleanroom.
      b. Dispose of elements of cleaning tools (pads, mop heads) in a method that minimizes the chance of dispersing contaminants in the air.
   iii. Cleaning and disinfecting supplies such as wipers, sponges, pads, and mop heads are made of low lint materials and, whenever possible are disposable.
      a. Disposable cleaning supplies are discarded after use.
      b. Reusable cleaning tools are made of cleanable materials that are nonporous (excluding wood) are are cleaned and disinfected before and after each use.
   iv. Clean compounding equipment used (e.g., mortar and pestle, cylinders, beakers, stir bars, etc.) as soon as possible after compounding is completed.
   v. Use the dedicated sink in the non-classified general pharmacy/lab area for cleaning compounding equipment and supplies.

g. **Documentation of Cleaning**
   i. Document all cleaning, disinfecting, and application of sporicidal disinfectants electronically within Simplfi 797 or on form **(F-0701)** in the event of system downtime (see **P-1802**) after

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completion of the task by the personnel performing the work. Detailed cleaning records are retained and readily accessible.

5. Definitions

a. **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).
b. **Cleaning agent:** An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
c. **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).
d. **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
e. **IPA:** Isopropyl alcohol.
f. **Low-lint wiper:** A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.
g. **One-step disinfectant cleaner:** A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
h. **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
i. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
j. **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.
k. **Sporicidal disinfectant:** A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
l. **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

6. Related Policies, Documents, References

a. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.

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7. SOP Major Change and Review Summary

Date	Section	Description of Change
12/03/2024	All	SOP Implementation
12/31/2024	All	Annual Review

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Section Name: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants	Policy Name: Remedial (Triple) Cleaning and Disinfecting Sterile Compounding Areas for Out of Specification Conditions
Policy Number/ Version: P-0703.1	Last Revision/Review Date: 12/31/2024

1. Overview and Scope

i. This policy describes the procedures for cleaning and disinfecting compounding areas where Compounded Preparations (CSP) are prepared within Source Pharmacy when an out of specification condition or remedial (triple) cleaning is required.
   i. As directed by the Designated Person or designee, perform and document remedial cleaning on an as needed basis. Remedial cleaning ranges from cleaning and disinfection to application of a sporicidal disinfectant to triple cleaning effected compounding areas.
   ii. A triple clean consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA 70%.
   iii. At a minimum, document purpose, date, and cleaning agent(s) used when conducting remedial cleaning. Ensure remedial cleaning documentation is retained and readily retrievable.

ii. Surfaces in classified areas and segregated compounding areas are potential sources of microbial contamination. In order to reduce the risk of contact contamination, surfaces within classified areas used to prepare Category 1, and Category 2, are cleaned, disinfected, and have sporicidal disinfectants applied according to the processes and frequencies described in this procedure.
   a. **Cleaning** involves removing organic and inorganic materials (e.g., dirt, debris, microbes, and residual drugs or chemicals) form surfaces with the use of a cleaning agent and manual or mechanical action.
   b. **Disinfecting** involves using a chemical or physical agent on surfaces to destroy microorganisms including fungi, viruses, and bacteria.
   c. **Sporicidal disinfectants** are a chemical or physical agents that destroys all vegetative microorganisms including bacterial and fungal spores while applied at a sufficient concentration and for a specified "wet" contact time.
   d. **Sterile 70% isopropyl alcohol (sIPA)** is a staple in day-to-day compounding activities and plays a critical role in sanitizing and reducing the bioburden on gloved hands, surfaces, and materials through both chemical application and physical wiping. sIPA 70%, however, is not a cleaning or disinfecting agent. While it does have some disinfectant properties, it does not possess the broad-spectrum coverage of cleaning, disinfecting, or sporicidal agents and requires a lengthy (and impractical) contact time to truly convey bactericidal or fungicidal activity.

2. Policy

a. Cleaning and disinfecting of all surfaces inside compounding areas, including sinks, as well as the application of a sporicidal disinfectant occur on a regular basis and at a minimum frequency as specified in USP <797> Pharmacecutical Compounding – Sterile Preparations 2022 and according to this policy **(see Section 4a).**
b. Surfaces in compounding areas are cleaned prior to being disinfected with an EPA-registered (or equivalent) agent. An EPA-registered (or equivalent) one-step disinfectant cleaner is an appropriate alternative that allows for both processes to occur in one step.

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c. Sporicidal disinfecting agents are EPA-registered (or equivalent) and allow for cleaning, disinfecting, and sporicidal activity concurrently in a single step.
d. Manufacturer's directions or published data for the minimum wet contact time is followed for each of the cleaning, disinfecting, and sporicidal agents used to ensure the agents have full microbial destroying action.
e. If compounding (and cleaning) is not performed each day, cleaning and disinfecting is completed before reinitiating compounding.
f. Cleaning and sanitizing is repeated when spills occur and when surfaces are visibly soiled.
g. All personnel involved in cleaning and disinfecting of classified compounding and segregated compounding areas receive training and demonstrate competency in Hand Hygiene and Garbing **(P-0301)** initially and at least annually. Refresher training is provided as needed and when changes in procedures or agents occur.
h. All cleaning and disinfecting activities are performed by appropriately garbed personnel using facility-approved agents and procedures including frequency, method, and location of cleaning activity.
i. Sterile cleaning agents are used to clean the interior of, and all equipment housed inside of PECs. Sterile cleaning agents are also used to clean SECs.
j. Cleaning agents and supplies used in PECs and SECs are assigned an expiration (or "in-use") date once opened or prepared; expiration dates are clearly and permanently written on the bottle, container, or wrapping of the supply and do not exceed manufacturer expiration dates or recommended "in-use" dates.

Cleaning Agent or Supply	Location Used	Expiration Date* (from initial puncture, use, or preparation)
Ready-to-Use (RTU) STERILE Cleaning, Disinfecting, and Sporicidal Agents	Inside PECs	30 Days
STERILE Premoistened or Low-Lint Dry Wipes	Inside PECs	30 Days unless wipes appear dry

k. Safety Data Sheets (SDSs) are retained for all cleaning supplies, included in training of cleaning personnel, and are readily retrievable by all compounding staff members.
l. Since cleaning solutions are irritants and can damage the skin and eyes, safety glasses must be worn during cleaning of ceiling and walls; during mixing of cleaning agents and on other occasions when there is an increased likelihood of splashing or dripping of solution.
m. Compounding equipment (*i.e. automated compounders, devices or pumps*) placed into ISO Class 5 PECs are subject to the same cleaning requirements as the LAFW itself. These devices must be moved during daily cleaning so that the surface underneath may be cleaned and disinfected

3. Roles & Responsibilities

a. Designated Person(s) (DP):

i. Ensures cleaning staff receives appropriate training and maintains current cleaning and related competencies.

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ii. Oversees selection of appropriate EPA-registered cleaning, disinfecting, and sporical agents and ensures staff understands and adheres to appropriate dwell times for each agent.
iii. Ensures the organization or facility maintains a current SDS for each cleaning agent in a readily retrievable format and location and ensures cleaning personnel understand how to access and use the SDS in case of a spill or accident.
iv. Determines appropriate remedial cleaning requirements for ad hoc and out-of-specification occurrences up to and including a triple clean of effected compounding areas including the following circumstances:
    a. Actionable environmental findings from total particle counts, viable air sampling, or surface sampling results and/or trends.
    b. Scheduled and unscheduled power and/or airflow disruptions directly impacting sterile compounding area(s).
    c. Certification of sterile compounding area(s).
    d. New or major construction or maintenance work performed within or adjacent to the sterile compounding area(s).

b. Compounding personnel:

i. Undergo training and demonstrate competency initially and at least once annually in skills and competencies related to cleaning and disinfecting **(F-0212)**.
ii. Adhere to all cleaning procedures **(P-0701-0703)** including cleaning agent selection, frequency, method, and sequence of cleaning activities (i.e., cleanest to dirtiest).
iii. Ensure appropriate use of sterile 70% IPA before, during, and after the compounding process.
iv. Complete timely documentation of all cleaning activities performed.

4. Procedures

a. Frequency of Cleaning, Disinfection, and Application of Sporicidal Disinfectants – Adapted from

	Cleaning and Disinfecting		**Applying Sporicidal Disinfectant**	
	Frequency	**Who**	**Frequency**	**Who**
Inside PECs – including all surfaces, direct compounding area and work tray, and equipment used inside the PEC	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency

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	Cleaning and Disinfecting		**Applying Sporicidal Disinfectant**	
	Frequency	**Who**	**Frequency**	**Who**
Work Surfaces Outside of PEC	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly – all surfaces including high touch and underneath of tables, chairs, and carts plus wheels.	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Floors	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Sinks	Daily	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Walls, Door(s), and Door Frame(s)	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency

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	Cleaning and Disinfecting		Applying Sporicidal Disinfectant	
	Frequency	**Who**	**Frequency**	**Who**
Ceilings of Sterile Suite	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Storage Shelves and Bins	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency
Equipment Outside of the PEC(s)	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency	Monthly	Pharmacy Technician, Compounding Pharmacist, DP, or any trained personnel that have completed both training and competency

i. Cleaning activities occur from cleanest to dirtiest areas. When performing cleaning, wipe from top to bottom in overlapping strokes so that the surface is thoroughly wetted but not dripping. Allow the cleaning agent PeridoxRTU (sporicidal agent) to dwell for 3 minutes and to dry on its own and disinfecting agent (sterile 70% IPA) to dry on its own. Do not wipe off or dry the surface since that will reduce the dwell time and render the agent less effective.

   a. To minimize odor, squeeze PeridoxRTU (do not use spray triggers) directly onto wipes and/or mop head to reduce odor. Cleaning agents must be applied to the applicator, not to the target surface.
   b. Apply only the amount of PeridoxRTU needed to clean the immediate area, while ensuring the applicator is sufficiently wet to facilitate achievement of dwell time per product label instructions.

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c. If excess PeridoxRTU is unintentionally applied, use a dry wipe, suitable for the controlled environment, to absorb the excess.

ii. Cleaning and disinfecting are performed as separate steps, cleaning is performed prior to disinfecting.

iii. After the application of a cleaning agent, or sporicidal disinfectant (PeridoxRTU), is allowed to dwell, or maintain a wet contact time, for the minimum duration of 3 minutes as specified by the manufacturer or published data to ensure full bactericidal, fungicidal, virucidal, and/or sporicidal action.

b. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in the PEC

i. If needed, remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.

ii. **For cleaning and disinfecting:** Use a sterile low-lint wiper and apply PeridoxRTU (a sterile cleaning agent) followed by a sterile IPA 70% a (disinfecting agent).

iii. Begin cleaning activity within the LAFW environment moving outward working from top to bottom and inner to outer surface. Note: Apply only the amount of PeridoxRTU Plus needed to clean the immediate area, while ensuring the applicator is sufficiently wet to facilitate achievement of dwell time (3 minute). Do not use spray triggers at any time on the HEPA filter with any cleaning or disinfectant solution. Carefully clean the HEPA grills. Order of cleaning of surfaces inside any PEC is as follows:

a. Ceiling inside the PEC which contains the HEPA filters in vertical flows.
b. Back surface which contains the HEPA filters in horizontal flows being careful not to splash the HEPA filter while cleaning the diffuser or protective screen.
c. Sides (left and right) as well as IV bar and hangers.
d. Anything on the deck (work surface of the PEC).
e. Deck itself.

iv. Ensure the wet contact/dwell time (3 minutes) specified by the manufacturer is achieved. If necessary, reapply to maintain a properly wet surface in order to achieve desired results.

v. After the application of cleaning, disinfecting, agent inside PEC, apply sIPA 70% to equipment and all interior surfaces to remove residue.

vi. Allow the surface to dry completely before beginning compounding. If daily cleaning was performed the night before, at the start of each new workday, the LAFW must be wiped down with a wipe wetted with sterile 70% IPA **(see Section 4c).**

a. **For application of a sporicidal disinfectant:** After cleaning and disinfecting, apply a sterile sporicidal disinfectant (PeridoxRTU) using a sterile low-lint wiper to all equipment, interior surfaces; since PeridoxRTU (the sporicidal disinfectant is an EPA-registered) is a one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required. Ensure the wet contact time of 3 minutes as specified by the manufacturer is achieved. If necessary, reapply to maintain a properly wet surface in order to achieve desired results.

vii. After the application of cleaning, disinfecting, and/or sporicidal agent inside PEC, apply sIPA 70% to equipment and all interior surfaces to remove residue.

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viii. Allow the surface to dry completely before beginning compounding. If daily cleaning was performed the night before, at the start of each new workday, the LAFW must be wiped down with a wipe wetted with sterile 70% IPA **(see Section 4c)**.

c. Use of Sterile 70% IPA inside of a PEC

i. Do not spray cleaning solutions, including sIPA 70%, inside of a PEC to avoid deteriorating the integrity of the HEPA filter. Wet a sterile low-lint wiper with the cleaning solution or sIPA 70% and apply directly with mechanical/manual action to the interior hood surfaces and equipment.

ii. Apply sIPA 70% to the horizontal work surface of each PEC and allow to dry before compounding:
   a. Immediately before initiating compounding or a new compounding process.
   b. At least every 30 minutes if the compounding process takes 30 minutes or less.
   c. After completing a compounding process if the process takes more than 30 minutes.

d. Other Cleaning Considerations

i. Clean high touch surfaces outside of PECs, including but not limited to:

High Touch Surfaces*	Other Surfaces
• Horizontal work surfaces, tables, counters, or carts • Chair seats, arms, and backs • Keyboards/keypads, mouse, RF scanner, touch screen monitors or tablets • Telephones and other communication devices • Light switches, door handles or hands-free activator • Sink surfaces, drain, and faucet • Gowning stool and storage bins	• Exterior of PECs • Legs, underside of horizontal surfaces, and feet/wheels of work surfaces, tables, counters, carts, chairs, or benches • Trash bins and hazardous waste disposal containers • Doorframes, window ledges, and other irregular surfaces •

ii. Cleaning, disinfecting, and the application of a sporicidal agent does not take place while active compounding is occurring.

iii. Perform cleaning from cleaner to dirtier areas (e.g. ISO 5, ISO 7, and then ISO 8 areas) therefore, the of the primary engineering controls (ISO Class 5 area) is cleaned first followed by the ISO Class 7 buffer area followed by the ISO Class 8 ante-area then general pharmacy preparation area.

iv. For all sites, clean and disinfect as needed after spills and when surface contamination (e.g., splashes) is known or suspected.

v. Replace all garb after cleaning and prior to resuming compounding duties; repeat hand hygiene and replace sterile gloves before returning to compounding.

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vi. Use appropriate respiratory support and eye protection when applying a sporicidal agent to surfaces within the compounding area, including the following cleaning tasks:
   a. Walls, ceilings, and floors.
   b. Surfaces outside of PECs.

e. Remedial Cleaning for Out of Specification Conditions

i. As directed by the Designated Person or designee, perform and document remedial cleaning on an as needed basis. Remedial cleaning ranges from cleaning and disinfection to application of a sporicidal disinfectant to triple cleaning effected compounding areas.
   a. A **triple clean** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA 70%.

ii. At a minimum, document purpose, date, and cleaning agent(s) used when conducting remedial cleaning. Ensure remedial cleaning documentation is retained and readily retrievable.

f. Selection and Use of Cleaning Agents

i. Select and use cleaning and disinfecting agents with careful consideration of compatibilities, effectiveness, and user safety including, but not limited to, antimicrobial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected.

ii. Use of ready-to-use and one-step disinfectant cleaner solutions is preferred over those requiring dilution or separate cleaning and disinfection steps.

iii. Clean and disinfect sterile cleaning agent containers prior to introduction into the ISO 5 environment per **P-0801.**

iv. Sterile cleaning and disinfecting supplies (e.g., closed containers of sterile wipers, bottles of 70% sterile IPA) can be used for up to 30 days once opened. Permanently and legibly write or label the expiration date on all cleaning supplies. Date opened, expiration date, and individual's initials but be clearly notated.

v. Store opened packages of sterile wipes inside of the PEC; if removed from a PEC once opened, they are no longer considered sterile and can only be used in ISO Class 7 and 8 areas. Disinfect sterile cleaning solution bottles stored outside of a PEC prior to introduction and use inside of the PEC with sIPA 70% per **P-0801.**

vi. Use sterile cleaning and disinfecting agents in all classified areas including PECs and SECs.

g. Selection and Use of Cleaning Supplies and Tools

i. Use sterile cleaning supplies (pads, mop heads) and tools inside; clean and disinfect prior to use (e.g., tool handles and holders).

ii. Dedicated reusable cleaning tools (e.g. mop frames and handles) are to remain in specific classified areas.

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a. Dedicated mop frames in buffer and ante rooms should never be removed. If removed following procedure **(P-0703)** for the introduction of equipment into the cleanroom.
b. Dispose of cleaning tools in a method that minimizes the chance of dispersing contaminants in the air.

iii. Cleaning and disinfecting supplies such as wipers, sponges, pads, and mop heads are made of low lint materials and are disposable.
a. Disposable cleaning supplies are discarded after use.
b. Reusable cleaning tools (mop frames and handles) are made of cleanable materials that are nonporous (excluding wood) are are cleaned and disinfected before and after each use.

iv. Clean compounding equipment used (e.g., mortar and pestle, cylinders, beakers, stir bars, etc.) as soon as possible after compounding is completed.

v. Use the dedicated sink in the non-classified/lab area for cleaning compounding equipment and supplies.

h. Documentation of Cleaning

i. Document all cleaning, disinfecting, and application of sporicidal disinfectants electronically within Simplfi 797 or on form **(F-0702)** in the event of system downtime (see Downtime **P-1802**) after completion of the task by the personnel performing the work. Detailed cleaning records are retained and readily accessible.

5. Definitions

a. **Classified area:** An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).
b. **Cleaning agent:** An agent for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
c. **Compounding area:** The area where compounding is occurring (i.e., a cleanroom suite or inside the perimeter of the SCA).
d. **Garb:** Items such as gloves, garments (e.g., gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle-shedding from personnel and minimize the risk of contamination of CSP(s).
e. **IPA:** Isopropyl alcohol.
f. **Low-lint wiper:** A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.
g. **One-step disinfectant cleaner:** A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
h. **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

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i. **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
j. **Segregated compounding area (SCA):** A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only.
k. **Sporicidal disinfectant:** A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
l. **Triple clean:** consists of two separate and distinct applications of an approved one-step disinfectant cleaner (allowing for full wet contact time between applications) followed by a separate application of an approved sporicidal disinfectant; remove cleaning agent residue with sIPA.

6. Related Policies, Documents, References

a. United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding- Sterile Preparations. 2022 version.
b. United States Pharmacopeial Convention, Inc. <800> Handling Hazardous Drugs in Health care Settings. 2019 version.

7. SOP Major Change and Review Summary

Date	Section	Description of Change
12/03/2024	All	SOP Implementation
12/31/2024	All	Annual Review

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Section Name: Handling, Storage, Packaging, Shipping & Transport	Policy Name: Out-Of-State Packaging & Shipping
Policy Number/ Version: 1905.1	Last Revision/Review Date: 10/06/2025

1. Overview and Scope

a. This policy describes the handling, storage, packaging, shipping, and transportation requirements and procedures for Compounded Sterile Preparations (CSPs) prepared at Source Pharmacy for patients that reside outside the state of Florida.

b. CSP quality and integrity can be adversely affected by inappropriate handling, storage, packaging, shipping, & transport methods. Care and consideration are given to the determination and selection of these methods and personnel and/or vendors to carry out these duties. Proper training, processes, quality assurance and control measures are integral to maintaining the quality of CSP during these processes.

2. Policy

a. Personnel handling, packaging, and shipping CSPs are trained in the knowledge and skills needed to perform job-related responsibilities. Refer to Sterile Compounding Personnel Training & Evaluation policy **(P-0204)** for further information.

b. CSPs are handled in a manner that maintains CSP quality and packaging integrity and are stored in temperature-controlled designated storage areas to ensure storage temperatures remain within the appropriate range prior to packaging and shipping.

c. Designated CSP storage area temperatures are monitored continuously via STAT Temp unless downtime procedures have been enacted, then the manual forms will be used.

d. CSP packaging materials protect CSPs from damage, leakage, contamination, degradation, and adsorption as well as prevent accidental exposure to transport personnel.

e. Tamper-evident closures are used for all CSPs shipped outside of Source Pharmacy.

f. Light-resistant packaging materials are used for light-sensitive CSPs.

g. Shipping and transportation methods and vendors are selected that reasonably and reliably deliver properly packaged CSPs in an undamaged, sterile, and stable condition.

h. CSPs delivered or shipped outside of Source Pharmacy bear the appropriate visible and legible labeling on the outer packaging or container conveying in-transit storage requirements, special handling instructions (if applicable), and immediate storage requirements (if appropriate) upon receipt. Refer to the Labeling of CSPs policy **(P-1301)** for further information.

3. Roles & Responsibilities

a. **Designated Person(s) (DP):**

i. Provides appropriate training and competency evaluations for personnel performing CSP handling, storage, packaging, and transport.

ii. Ensures CSP storage locations are appropriately monitored, and temperature is recorded daily or readily accessible.

iii. Researches CSP stability and integrity when drug storage temperature excursions occur and determine if CSPs have retained quality and can be dispensed or must be destroyed due to a lack of uncertainty in the available stability and sterility data in the event of an excursion.

iv. Ensures packaging procedures and materials are appropriate to help retain the quality of the CSP.

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b. Internal Personnel Handling, Storing, Packaging, & Transporting CSPs:

i. Personnel successfully complete and remain current on training and competency assessments required to perform job functions. Refer to Sterile Compounding Personnel Training & Evaluation policy **(P-0204)** for further information.

c. Third Party Delivery and Shipping Vendors:

i. Maintain appropriate CSP storage conditions during transit per labeling and delivery or shipping instructions.

4. Procedures

a. CSP Packaging

i. Select CSP container closure systems and packaging that do not interact physically or chemically (e.g., adsorption) with the CSP and that protect the CSP's sterility, identity, potency, purity, and similar quality criteria (e.g., light sensitivity).
   a. Refer to the USP-NF drug monograph, manufacturer's packaging data, or similar literature to determine appropriate container closure systems and packaging.
   b. Record container closure system and packaging requirements and references on the Master Formulation Record (MFR), if applicable, for future reference.

ii. Use tamper evident CSP containers or closure systems for the following:
   a. Controlled substance CSPs.
   b. Ophthalmic and Otic CSPs.
   c. CSPs transported or shipped to an offsite administration site or directly to the patient.
   d. CSPs delivered, transported, or shipped by a third-party vendor.

iii. Prior to transport outside of the pharmacy, package CSPs in packaging materials that minimize the risk of damage, leakage, or contamination and are designed to maintain the integrity of the requisite storage conditions for each CSP. Acceptable packaging includes, but is not limited to:
   a. **Containers:** Hard-sided coolers, insulated containers, and/or refrigerated or frozen storage units.
   b. **Cooling Source:** Ice packs, refrigerant cooling blocks, or dry ice.

c. CSP Delivery, & Shipment

i. For transport and delivery outside of the immediate facility, package CSPs individually in clear zippered bags to minimize the risk of contamination or spill exposure to transport personnel and use appropriate packaging and devices (e.g., insulated cooler) to maintain storage conditions during transport.

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Transport Scenario/Storage Conditions	Required Packaging Materials		
	Controlled Room Temp 20°C - 25°C (68°-77°F)	Refrigerated: 2°C - 8°C (35.6°-46.4°F)	Frozen: -25°C to - 10°C (-13° to 14°F)
Transport within immediate facility via cart	• CSP(s) placed in sanitized bins	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs
Transport or delivery to locations outside of immediate facility	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs	• CSP(s) placed in clear zippered bag • Transported in cooler with ice packs	• CSP(s) placed in clear zippered bag • Transported in cooler with dry ice
Transport Scenario/Storage Conditions	**Required Packaging Materials**		
	Controlled Room Temp 20°C - 25°C (68°-77°F)	**Refrigerated: 2°C - 8°C (35.6°-46.4°F)**	**Frozen: -25°C to - 10°C (-13° to 14°F)**
Shipping via Common Courier	• CSP(s) placed in clear zippered bag • Packaged in insulated container with ice packs.	• CSP(s) placed in clear zippered bag • Packaged in insulated container with ice packs or dry ice.	• CSP(s) placed in clear zippered bag • Packaged in insulated container dry ice.

*Refer to Dry Ice Use policy for safe handling procedures.

ii. When transporting or shipping CSPs outside of the immediate facility, package CSPs in shipping containers designed to protect and maintain the quality of the contents and secured in a manner that allows for immediate detection of tampering or unauthorized entry into the shipping container.

iii. For temperature sensitive CSPs, package the CSP in a moisture resistant clear, zippered bag placed inside of an appropriate insulated shipping container.

iv. Label external shipping containers, special handling instructions, in-transit storage requirements and immediate storage requirements upon receipt if appropriate.

d. Monitoring & Logging Storage Temperatures

i. Monitor and log temperatures of all drug storage locations and devices daily on days of operation.

ii. Temperatures are monitored continuously via STAT Temp unless downtime procedures have been enacted, at which time manual logs to be utilized.

iii. Temperature monitoring devices are maintained, and accuracy validated at least once every 12 months or per manufacturer instructions. All equipment for testing and certification is calibrated per Intitute of Environmental Sciences and Technology (IEST) standards or manufacturer's recommendations and calibration dates documented.

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iv. Retain readily retrievable records of temperature logs and accuracy validations.

e. CSPs Exposed to Temperature Deviation during Transport or Shipping

i. Provide delivery personnel and vendors transporting CSPs within and outside of the immediate facility with training and instructions regarding:
   a. Monitoring CSP temperatures, packaging, and storage conditions before, during, and immediately after transit.
   b. Managing and reporting temperature deviations and excursions.

ii. When temperature excursions are reported to the Pharmacy, log the issue per the Complaints, Adverse Drug Reactions, & CSP Recall policy **(P-1801)**.

5. SOP Major Change and Review Summary

Date	Section	Description of Change
10/06/2025	All	SOP Implementation

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Section Name: Handling, Storage, Packaging, Shipping & Transport	Policy Name: Maintaining Shipping Integrity
Policy Number/ Version: P-1904.1	Last Revision/Review Date: 10/06/2025

1. Overview and Scope

a. This policy describes the packaging required to maintain the temperature/storage conditions of CSP during the shipping and transportation process. Defined within are the requirements and procedures for shipping any Compounded Sterile Preparations (CSPs) prepared at Source Pharmacy.

b. CSP quality and integrity can be adversely affected by inappropriate handling, storage, packaging, shipping, & transport methods. Care and consideration are given to the determination and selection of these methods and personnel and/or vendors to carry out these duties. Proper training, processes, quality assurance and control measures are integral to maintaining the quality of CSP during these processes.

2. Policy

a. Personnel handling, storing, packaging, and transporting CSPs are trained in the knowledge and skills needed to perform job-related responsibilities. Refer to Sterile Compounding Personnel Training & Evaluation policy **(P-0204)** for further information.

b. CSPs are handled in a manner that maintains CSP quality and packaging integrity and are stored in temperature-controlled designated storage areas to ensure storage temperatures remain within the appropriate range.

c. CSP packaging materials protect CSPs from damage, leakage, contamination, degradation, and adsorption as well as prevent accidental exposure to transport personnel.

d. Tamper-evident closures are used for all CSPs shipped outside of Source Pharmacy.

e. Light-resistant packaging materials are used for light-sensitive CSPs.

f. Shipping and transportation methods and vendors are selected that reasonably and reliably deliver properly packaged CSPs in an undamaged, sterile, and stable condition.

g. CSPs delivered or shipped outside of Source Pharmacy bear the appropriate visible and legible labeling on the outer packaging or container conveying in-transit storage requirements, special handling instructions (if applicable), and immediate storage requirements (if appropriate) upon receipt. Refer to the Labeling of CSPs policy **(P-1301)** for further information.

3. Roles & Responsibilities

a. Designated Person(s) (DP):

i. Provides appropriate training and competency evaluations for personnel performing CSP handling, storage, packaging, and transport.

ii. Ensures packaging procedures and materials are appropriate to help retain the quality of the CSP.

b. Personnel Packaging, & Shipping CSPs:

i. Personnel successfully complete and remain current on training and competency assessments required to perform job functions. Refer to Sterile Compounding Personnel Training & Evaluation policy **(P-0204)** for further information.

ii. Personnel will be trained and validated for properly and safely packaging medications for shipping and transport. Personnel will be trained to select packing containers and materials that maintain physical integrity, stability, and sterility of compounded preparations.

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c. **Third Party Delivery and Shipping Vendors:**
   i. Maintain appropriate CSP storage conditions during transit per labeling and delivery or shipping instructions.

4. Procedures

a. **Order/Data Entry**
   i. Upon receipt of a prescription for an out-of-state patient the data entry personnel will, enter the requested shipping method in the "Delivery Hand-Off Method" field within Pharmetika. In the event a method is not notated on the original prescription the employee will contact the patient to discuss options.
   ii. Should additional details or special instructions be required, they will be entered in the appropriate note section for the prescription in order to facilitate communication with the personnel responsible for preparing the final shipment.

b. **CSP Packaging/Shipping Preparation**
   i. Only medication/prescriptions that have been through the complete dispensing process in Pharmacist verification steps 1 and 2 can be packaged and prepared for shipping.
   ii. Packaging/storage conditions are clearly indicated on all patient prescription labels. This information was determined by utilizing all information available about a product or compounded preparation e.g., product package insert, compounded preparation-USP, to determine shipping precautions to maintain the integrity of the product or compounded preparation.
   iii. Place the medication in the appropriate shipping container. Select packing containers and materials based on product/ preparation specifications, experience, vendor requirements, mode of transportation, prevention of unintended exposure to transport personnel and that are expected to:
      a. Maintain physical integrity
      b. Sterility
      c. Stability of the compounded preparation during transit
      d. Protect from light if required
      e. Protect from temperature fluctuations
      f. Protect from adsorption
      g. Protect from damage
      h. Protect from leakage
      i. Protect from contamination
      j. Protect from degradation
      k. Protect transport personnel from harm
      l. Protect recipients from harm
   iv. Pack compounded preparations according to the storage requirements and special packaging requirements in the preparation's Master Formula Record, SOP: Basic Compounding Documentation—The Master Formula Form.
      a. If colder than controlled room temperature is required for storage of a finished preparation then use a cold method to ship.
      b. The designated responsible person will determine if a temperature monitoring device is placed in the packaging container used to ship finished preparations.

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c. Tamper-evident closures to protect the quality of preparations
d. Light resistant packaging for light sensitive preparations

v. Seal the shipping container.

c. Preparing the Package for Shipment

i. Determine the mode of transport (e.g., overnight, regular ground shipping) using the following criteria list (this list may not be inclusive) in the event one has not been indicated upon prescription entry:
   a. Delivery of the compound preparation is in undamaged and stable condition.
   b. Expected delivery date
   c. Climate conditions in transit
      i. A compounded preparation transit temperature cannot exceed the warmest specified temperature range on its label.
      ii. When common carriers are used, refrigerated products should use an exterior "Refrigerate" marking.
   d. Protection against over shaking
   e. Specific handling instructions when stability is a concern.

ii. Complete a shipping label to include the pharmacy's name and address on the label and the patient's name/third party recipient and mailing information, confirming that the shipping label information is correct.
   a. To protect patient confidentiality, prescription labels with medication names and directions should not be used to label boxes. Box labels should include only the patient's name and address, the storage requirements, and delivery instructions

iii. Affix the shipping label onto the appropriate shipping container.

iv. Add instructions that clearly explain how to safely open containers and attach them to the outside of the container.

v. Add written instructions or labeling that clearly explains how to properly store and handle the containers contents and attach to the outside of the container.

vi. Add written instructions that clearly explain how to safely dispose of used or out-of-date containers/units.

vii. Place the packaged prescription and other supplies in the appropriate waiting bin/area, near the Shipping Log.

d. Timing & Confirmation

i. No shipment of temperature sensitive medications will be processed on a Friday unless Saturday delivery is specifically noted, and available for the recipient's address.

ii. No shipment of temperature sensitive medication will be processed the day preceding a National Holiday, unless confirmation can be obtained that service level required is available for the recipient's address.

iii. All Friday shipments must be reviewed to prevent shipments being handled/stored by the 3rd party carrier over the weekend and to ensure no disruption of therapy will occur as a result of these restrictions.

iv. If appropriate, notify the patient/third party recipient when they may expect their prescription/preparation.

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v. Request delivery confirmation from the courier company on a periodic basis to ensure packages are arriving on time and in useable condition. Include delivery confirmation as a monitoring index for quality assurance.

vi. Request that the patient notify the pharmacy if the prescription is not received with the expected timeframe.

f. Quality assurance

i. Periodically review the delivery performance of the courier company. A monitoring index is included in the Investigation Forms and will be periodically reviewed, at least annually, for Performance.

ii. Periodically review the delivery performance of shipments that require special treatment i.e. heat sensitive, cold sensitive. A monitoring index is included in the Investigation Form and will be periodically reviewed, at least annually for performance e.g., semi-annually ship to self or check with recipient and document result, one time each in the summer (warmest time) and winter (coldest time).

iii. If a temperature sensitive indicator is used, develop an education sheet to be sent with the delivery to the end user explaining the interpretation process for success or failure of a temperature sensitive indicator and therefore the state of the product/ preparation.

iv. Consider developing a set of questions to quiz the end user about the arrival condition of the shipping container if the quality assurance process includes speaking to the end user. This will aid in the evaluation of the success or failure of the shipped process.

5. SOP Major Change and Review Summary

Date	Section	Description of Change
10/06/2025	All	SOP Implementation

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1889423		**Inspection Information**
Legal Business Name:	Cubance, LLC	**Conference Call Date:**	9/22/2025
Doing Business As (DBA):	Source Pharmacy	**Start Time: 24-hour format (13:00)**	14:00
Address:	8170 Okeechobee Blvd, Ste 4	**End Time: 24-hour format (13:00)**	15:22
City:	West Palm Beach	**Onsite Inspection Date(s):**	09/24/2025 & 09/25/2025
State:	Florida	**Start Time(s): 24-hour format (13:00)**	09:00 & 09:00
Zip Code:	33411	**End Time(s): 24-hour format (13:00)**	14:46 & 12:32
Telephone number:	855/437-7316	**Inspector Name(s):**	Glenn Bolyard, RPh
Toll free number:	855/437-7316	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	561/666-4018	**Observer Name/Affiliation (if applicable):**	N/A
Website:	https://sourcerx.health/	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy - 15.00, 47.00, 47.05, 47.07, 47.10, 93.00
Sterile - 17.0 and 17.3

Additional information on NABP's Inspection website.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	9:00	15:00	
Tuesday	9:00	15:00	
Wednesday	9:00	15:00	
Thursday	9:00	15:00	
Friday	9:00	15:00	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Joseph (Joe) Coyne	joe@sourcerx.health	532722
Nonsterile Designated person(s)	N/A	N/A	N/A
Sterile Designated person(s)	Joseph (Joe) Coyne	joe@sourcerx.health	532722
Hazardous Designated person(s)	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Joseph Coyne	PIC	Y
2	Amah Edwards	Pharmacist	Y
3	Jessica Lynch	Pharmacy Technician	Y
4			
5			
6			
7			
8			
9			
10			

There were no other personnel present at time of inspection. These are the only employees at the pharmacy.

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Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Florida Board of Pharmacy	Cubance LLC Source Pharmacy	Pharmacy	PH35647 & 2/28/2027
Florida Board of Pharmacy	Cubance LLC Source Pharmacy	Sterile Compounding	PH35647 & 2/28/2027
Drug Enforcement Administration	Cubance LLC Source RX	Pharmacy	FC4852237 & 8/31/2027

Inspector Notes: The pharmacy has a pharmacist designated as PIC for Texas. His name is Gregory Brown, Texas license #59740. He is a pharmacist working under common ownership next door at Progress Pharmacy. The pharmacy has non-resident licenses in Arizona, Colorado, Idaho, Montana, New York, Pennsylvania, South Dakota, Wisconsin and Wyoming. The pharmacy will be applying for a Massachusetts license. The pharmacy does not use any platform that is a marketplace for pharmacists to buy, sell, and bid on overstock and short date prescription drugs. The pharmacy does not perform white bagging. There wasn't any ReliOn insulin on site. A copy of COA for each API used for compounding is Doc02_PI. A list of compounds made by the pharmacy is listed as Doc03_PI. The pharmacy is compounding semaglutide and tirzepatide. A copy of COA, MFR, CR of both semaglutide and tirzepatide are Doc04_PI. A picture of semaglutide API used is Photo01_PI and Photo02_PI, photos do not indicate base or salt. The pharmacy is not following an ARB study. Batch size is typically 25-50 with 59 patients receiving this prep in the past month. There are currently only 3 employees in this pharmacy.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_PI	Example of drug counseling flyer mailed to patient.
Doc02_PI	COA of each API used for compounding.
Doc03_PI	List of compounds made by the pharmacy.
Doc04_PI	COA, MFR and CR for both semaglutide and tirzepatide compounds.
Photo01_PI; Photo02_PI	Photos of semaglutide API.

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	X
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)	X	Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	X
Internet/Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	X
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	X
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	X
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	X
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	X
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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	Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel
Total Pharmacy size:	1,200	Total Pharmacists:	2
Nonsterile Compounding Room size:	N/A	Number of Compounding Pharmacists:	1
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Technicians:	1
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Number of Compounding Technicians:	1
Sterile Compounding Ante Room size:	49	Of technicians, how many are nationally certified?	1
Sterile Compounding Clean/Buffer Room size:	63	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	1	Total Other Unlicensed Personnel:	0
Sterile Compounding Number BSC hoods:	1	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	1:1
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	Semaglutide 2mg/ml with Cyanocobalamin 180mcg/ml 3ml vials #25
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	Inspector did not garb and enter buffer room since glass easily allowed viewing of rooms and compounding. Pictures taken on iPad showed precise measuring of API.

	Volume Dispensed		Volume Distributed
Total Prescriptions Dispensed/day:	15	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	100%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)	4	0	9/1/2025 - 9/5/2025
Arkansas (AR)			
California (CA)			
Colorado (CO)	21	0	9/1/2025 - 9/5/2025
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)	58	0	9/1/2025 - 9/5/2025
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)	4	0	9/1/2025 - 9/5/2025
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)	0	0	9/1/2025 - 9/5/2025

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)	9	0	9/1/2025 - 9/5/2025
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)	7	0	9/1/2025 - 9/5/2025
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)	10	0	9/1/2025 - 9/5/2025
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)	0	0	9/1/2025 - 9/5/2025
Wyoming (WY)	2	0	9/1/2025 - 9/5/2025
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

	General Pharmacy	Observation	Notes
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	N/A	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Amah Edwards, Pharmacist; Jessica Lynch, Pharmacy Technician

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		Observation	Notes
Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**			
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	No	Licenses are current but they are located on both the right and left walls going down the hallway in the pharmacy area itself. This is not accessible to the customer.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The Florida BOP had 2 inspections due to opening a new pharmacy. The first inspection was for Sterile Compounding on 3/6/2025. The second inspection was for Community Requirements on 5/6/2025. Florida BOP routinely inspects yearly.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	IPA used during demonstration and stored in hood for cleaning was expired. Documentation does not show the starting temperature of each stage of incubation. Open and undated bottles of IPA and Peridox being used. Five bottles of IPA had expired manufacturer dates. These were all corrected.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	Yes	Inspection date was 10/1/2024. Joseph Coyne, PIC, stated there were no deficiencies and there was not a physical report left with the pharmacy.
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	

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e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Notes
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	No	Records will be kept for 5 years on site per P&P. The pharmacy has only been opened since 3/19/2025.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	No	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	The prescription can be inactivated but not deleted.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	Yes	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Joe Coyne, PIC, keeps all regulations electronically and subscribed to all state website newsletters.

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e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Notes
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented*	Yes	Licenses are checked yearly and periodically but there is no documentation.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Joseph Coyne, PIC, gets a hard copy of each license and performs primary source verification.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	The ratio is 1:2 which is the maximum number of staff who work at the same time. This pharmacy only has 1 technician and recently hired a second pharmacist.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Exclusive Protection Systems is the alarm system in place. This includes a magnetic door alarm, motion detector and camera in the front entrance area. Keypad alarm is to the right inside the front door. Only pharmacists have alarm codes. All alarming and disarming the pharmacy is electronically maintained. There is not a back door to the pharmacy. The only motion detector is in the entrance.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	There are no controlled drugs at this pharmacy.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Drugs would be relocated to another licensed facility. Pharmacist would stay on site until relocated.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	

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e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Notes
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No destruction on site.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	N/A	No reverse distributor as the pharmacy is new. Holding return prescription products in a quarantined area until hire reverse distributor.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Daniels Medical supplies Sharps collection devices. There is once a month collection and there are digital records on site.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	There is a counseling area to the left inside the front door.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	There is continuous temperature monitoring by Stat Temp. Temperature at time of inspection was 17.8°C.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	There is continuous temperature monitoring by Stat Temp. Excursions are sent to Joseph Coyne, PIC, by phone during business hours and after hours by text. He must acknowledge before alerts will cease. Inspector verified acknowledgement and resolution electronically by Stat Temp.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	There is continuous temperature monitoring by Stat Temp. Excursions are sent to Joseph Coyne, PIC, by phone during business hours and after hours by text. He must acknowledge before alerts will cease. Inspector verified acknowledgement and resolution electronically by Stat Temp. Records are maintained indefinitely. Range is 2° - 8°C .

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e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Notes
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Current temperature is 6°C.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	There is continuous temperature monitoring by Stat Temp. Excursions are sent to Joseph Coyne, PIC, by phone during business hours and after hours by text. He must acknowledge before alerts will cease. Inspector verified acknowledgement and resolution electronically by Stat Temp.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	Yes	Current temperature is -14°C.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Drugs would be relocated to another licensed facility. Pharmacist would stay with product until relocated. Contracted vendor would be contacted to fix the issue.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Drugs would be relocated to another licensed facility. Pharmacist would stay with product until relocated. Contracted vendor would be contacted to fix the issue.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

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Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Unknown	Joseph Coyne, PIC, stated there is a vendor selection policy which includes validating vendor licenses with the Florida BOP. There is no documentation available at the pharmacy to show inspector.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Medisca, PCCA, Fagron, Spectrum, Darmerica, Biopeptek
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	Joseph Coyne states he has verified this through verbal confirmation.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes. Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Unknown	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	Joseph Coyne, PIC, verifies licenses with the state of Florida.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	Joseph Coyne, PIC, stated he is still under exemption until 1/2026.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The pharmacy would quarantine the product and open an investigation with the wholesaler.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	New pharmacy that has not had any product investigations.

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		Observation	Notes
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	Joseph Coyne, PIC, was not aware of 3T data. Recent purchases were examined electronically but 3T data was not noted on the invoices observed.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	There are no controlled drugs at this pharmacy.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory by software system and monthly checks by Joseph Coyne, PIC.

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		Observation	Notes
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Florida Board of Pharmacy and local law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	N/A	
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Out of dates are checked monthly.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	Shelves, refrigerator and freezer were checked for expiration dates.

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		Observation	Notes
60.02	How often is active-stock examined for drugs past the expiration date?		Out of dates are checked monthly.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Pharmacy technician or pharmacist performs data entry. This information is updated on a refill or new prescription.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	The pharmacist looks for red flags along with checking patient addresses and contacts the physician with any concerns.

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		Observation	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The pharmacist looks for red flags along with checking patient addresses and contacts the physician with any concerns.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Non-controlled substances.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Data entry by technician and it is verified by a pharmacist. The pharmacy process includes a Data Entry, PV1 by pharmacist, Filling process by technician and PV2 Final Verification by pharmacist.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR is performed at PV1.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	No	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Lexicomp and USP Compounding Compendium all of which is online.

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		Observation	Notes
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	The pharmacy reports to all states dispensed.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	The pharmacist has the capability to override DUR and it is logged in the prescription record.
67.07	Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	Yes	Pharmetika
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	The pharmacist verifies filled prescriptions at PV2 prior to dispensing and it is documented in the prescription records.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Labels contain all federal and state required information including it is a compound drug, beyond use date, quantity, ingredients, date, physician, pharmacy name and contact information, storage requirements, route of administration and patient name.
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Pharmetika

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		Observation	Notes
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Observation	Notes
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	Yes	The pharmacist makes the offer.
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	Yes	The pharmacist makes the offer.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	Yes	The pharmacist makes the offer.
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	The pharmacy does not deliver medications.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	There is a printout included with the specific drug dispensed. This includes counseling information as well as the pharmacy contact information (Doc01).

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		Observation	Notes
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	N/A	There are no drugs dispensed that require PPIs.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	There are no drugs dispensed that require MedGuides.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for Isotretinoin, or Tikosyn).*	N/A	The pharmacy does not implement REMS programs.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	The computer software tracts the patients acceptance or denial of counseling.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	The patient would call the patient and the answering service would contact a pharmacist to contact the patient.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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		Observation	Notes
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Joseph Coyne, PIC oversees the program and reports findings to senior leadership.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Both
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Both
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	

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		Observation	Notes
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Joseph Coyne, PIC, performs the analysis with each event.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	Yes	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	

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National Association of Boards of Pharmacy®
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General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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		Observation	Notes
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	MedWatch and Florida Board of Pharmacy
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	Complaint process that is documented.

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Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
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		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)		**Please note NABP did not review each SOP for alignment on USP <797>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions." If no, go to compliance statements.***	Yes	Board certified in Sterile compounding, 30 plus years as compounder. Was employed at Critical Point for 3 plus years.	1.1.3, 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. ***Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality."***	Yes		2, 4.2, 4.5

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		Observation	Inspector Notes	USP Reference(s)
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. ***Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.***	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes	The pharmacy has their own training competency program.	2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. ***Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."***	Yes		2, 5, 12

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		Observation	Inspector Notes	USP Reference(s)
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding processes and other support activities in compliance with USP <797> standards? ***Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.*** ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		17
2.1	**Scope of Practice:** Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		P-0101 P-0202	1.5
2.2	**Personnel Training and Evaluation:** Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform restocking or cleaning, and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and garbing competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		P-0204 P-0301 P-0901	2, 2.2, 10 Box 1, Box 2, Table 2, Table 3
2.3	**Personal Hygiene and Garbing:** Description of the required garb, manner of storage, and order of garbing, including disinfection procedures for reusing goggles, respirators, and other reusable equipment. ***Inspector note: Per USP, the RABS (or pharmaceutical isolator) sleeve and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.***		P-3001	3, 3.3

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		Observation	Inspector Notes	USP Reference(s)
2.4	**Facility Design and Engineering Controls:** Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		P-0401	4, 4.2
2.5	**Certification and Recertification:** Description of sampling sites and procedures.		P-0501	5, 5.1
2.6	**Microbiological Air and Surface Monitoring:** Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that will trigger corrective actions and documentation requirements.		P-0601 D-0601.1	6, 6.1, 6.2, 6.3
2.7	**Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA:** Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		P-0701 P-0702 P-0703	7, 7.2 Box 7, Box 8
2.8	**Equipment:** Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		P-0901	9.1, 10, 20

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		Observation	Inspector Notes	USP Reference(s)
2.9	**Components:** Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and container closures.		P-0901	9.3
2.10	**Master Formulation and Compounding Records:** Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CRs.		P-1101	11.1, 11.2, 20
2.11	**Release Inspections and Testing:** Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specification procedures, corrective action procedures, and documentation requirements.		P-1201	12, 18, 20
2.12	**Labeling:** Procedures for labeling and label verification (confirming against the prescription or medication order, the MFR, and the CR) in order to prevent errors, CSP mix-ups, and required displayed information.		P-1301	13
2.13	**CSP handling, storage, packaging, shipping, and transport:** Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, excursions, shipping containers, packaging requirements, and selected transportation modes.		P-1902	19
2.14	**Documentation:** Record keeping requirements and procedures for documentation maintenance and storage. ***Inspector note: USP requires readily retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.***		P-2001	20

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		Observation	Inspector Notes	USP Reference(s)
2.15	**Sterilization and Depyrogenation:** Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. ***If not applicable to their business practices, inspector should answer statement as N/A.***		P-1803	10
2.16	**Immediate Use CSPs:** Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3 CSPs. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.3
2.17	**Blood/Biological Handling:** Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	1.1.2
2.18	**Allergenic Extracts:** Description of procedures for training, competency assessments, personnel hygiene and garbing, facility requirements, cleaning and disinfecting, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. ***If applicable to their business practices, please complete the Allergenic Extracts module.*** ***If not applicable to their business practices, inspector should answer statement as N/A.***		N/A	21

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		Observation	Inspector Notes	USP Reference(s)
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood-Derived			1
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? ***Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.***	N/A		1.3
4.1	Aseptic techniques, processes, and procedures are followed. ***Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."***	N/A		1.3
4.2	Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs. ***Review personnel records to verify.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. ***Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.***	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (eg, ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (ie, single-dose containers are not used for more than one patient).	N/A		1.3
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. ***If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.***	N/A		1.3

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		Observation	Inspector Notes	USP Reference(s)
5.0	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? ***Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.*** ***If no, go to compliance statements.*** ***If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.***	N/A		1.4
5.1	Docking for *future activation* and administration is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? ***Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.*** ***If no, go to compliance statements.*** ***If the pharmacy only <u>compounds</u> sterile preparations (eg, does <u>not</u> prepare sterile preparations that strictly adheres to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.***	N/A		1.4

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		Observation	Inspector Notes	USP Reference(s)
6.1	The product is prepared as a single dose for an individual patient.	N/A		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	N/A		1.4
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	N/A		1.1.2
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? ***Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.*** ***If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.***	N/A		1.1.2

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		Observation	Inspector Notes	USP Reference(s)
	Facility Design and Engineering Controls			4
9.0	**Segregated Compounding Area (SCA):** Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.*** ***If no, go to compliance statements.*** ***If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.***	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1
9.2	Only Category 1 CSPS are prepared in a SCA. ***If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.***	N/A		4.2.1, 4.2.3 Table 5
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	N/A		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.4	The SCA is located away from environmental control challenges and separate from areas not related to compounding (ie, restrooms, warehouses, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. ***Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classifled space.***	N/A		4.2.1 Glossary
9.6	Access to the SCA is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.***	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. ***Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).***	N/A		4.5

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		Observation	Inspector Notes	USP Reference(s)
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? ***If no, describe observations in Inspector Notes.***	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments Inspector Notes (eg, peeling of Formica countertops).***	Yes		4.3.2

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		Observation	Inspector Notes	USP Reference(s)
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? ***Inspector note: this is a recommendation by USP.*** ***If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).***	Yes		4.2.1, 4.3.2
12.0	**Cleanroom Suite:** Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? ***Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs.*** ***If no, go to compliance statements.*** ***If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.***	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5
12.1	Access to the cleanroom suite is restricted to authorized personnel. ***Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with this statement (but are not specifically required by the chapter) include posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.***	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings so appropriate garb can be donned).	Yes		4.2.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by fixed walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. ***Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."***	Yes		4.2.1
12.6	Anterooms providing access to only positive pressure buffer rooms meet at least ISO Class 8 specifications. ***If the pharmacy has a negative pressure room, inspector should answer statement as N/A.***	Yes		4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. ***If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.***	N/A		4.1.2, 4.2.1
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. ***Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.*** ***Per USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.***	Yes		4.1.2, 4.2.1, 4.2.3

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		Observation	Inspector Notes	USP Reference(s)
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. ***If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.***	Yes		4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/placement changes when air returns are not located low on the wall. ***Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, chapter of HEPA filter units)."*** ***If air returns are low on the wall, inspector should answer statement as N/A.***	Yes		4.2.1
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. ***Describe observations for the type of line of demarcation in the Inspector Notes.***	Yes	Line of demarcation is tape on the floor.	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. ***If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polymer) and integrity of surface maintained.	Yes		4.2.1, 4.3.1
12.18	Walls, if paneled, are joined together and sealed to the support structure. ***If walls are not paneled, inspector should answer statement as N/A.***	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the juncture between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. ***If there are no overhangs, ledges, utility pipes, windowsills, etc, Inspector should answer statement as N/A.***	Yes	Easily cleanable ledges.	4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.21	Exterior lens surfaces of the ceiling light fixtures are smooth, mounted flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, camera domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4
13.0	Are **PECs** used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? ***Inspector to review certification reports and observe compounding area(s) to evaluate.*** ***If no, go to compliance statements.***	Yes	Reports reviewed.	4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. ***The inspector should only answer yes if the PEC has been certified within the past six months.***	Yes		4.2.2, 4.2.3, 5

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		Observation	Inspector Notes	USP Reference(s)
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. ***Review certification report.***	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3
13.5	**Category 2 and Category 3:** PEC(s) are located in a cleanroom suite. ***If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.2.3 Table 5
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3 Table 5
15.0	Are **CAIs/CACIs** (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications **and** USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. ***Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.***	N/A		4.2.3
15.3	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. ***Inspector note: Per USP, If using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.***	N/A		3.3
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? ***Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.*** ***If no, go to compliance statements.***	Yes		4.5

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		Observation	Inspector Notes	USP Reference(s)
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (providing that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? ***If no, go to compliance statements.***	No		4, 9.1, 19.1
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. ***Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA. Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.*** ***If the sink is located in the anteroom, inspector should answer statement as N/A.***	N/A		4.4

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		Observation	Inspector Notes	USP Reference(s)
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. ***Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where garb is stored (where it can easily get wet/splashed).*** ***If the sink is located outside the anteroom, Inspector should answer statement as N/A.***	Yes		4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	No		4.2.1
17.4	The inside and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	N/A	There is not a pass-through in this pharmacy.	4.2.1
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. ***Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected.*** ***If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.***	Yes		4.5, 9.1
17.6	Tacky mats are not used in the classified areas. ***Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."***	Yes		4.2.1

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		Observation	Inspector Notes	USP Reference(s)
17.7	Shipping cartons or other corrugated or uncoated cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels.	Yes		4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes		4.5
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? ***Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.*** ***If no, go to compliance statements.***	Yes		4.2, 19.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. ***If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.***	Yes		4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2, 9.3.4, 19.1
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. ***If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.***	Yes		4.2, 9.3.4, 19.1
18.4	The pharmacy maintains records of temperature and humidity that are specific to the cleanroom suite. ***Temperature and humidity for drug storage areas will be documented in the general pharmacy module.*** ***If the pharmacy only uses an SCA, inspector should answer statement as N/A.***	Yes		4.2, 9.3.4, 19.1
18.5	The pharmacy can readily retrieve temperature and humidity records. ***If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."***	Yes		4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
18.6	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. ***Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.***	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. ***Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).***	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	Calibrated annually by Technical Maintenance Incorporated.	4.2, 9.3.4
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Monitoring devices are typically calibrated or replaced.***	Yes	Calibrated annually by Technical Maintenance Incorporated.	4.2, 9.3.4

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		Observation	Inspector Notes	USP Reference(s)
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? ***Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.***	No		4.2, 9.3.4, 19.1
20.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	N/A		4.2, 9.3.4, 19.1
21.0	What is the current temperature of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		19°C.	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? ***Record in the Inspector Notes.***		49%	4.2, 9.3.4, 19.1
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1

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		Observation	Inspector Notes	USP Reference(s)
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? ***Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.*** ***If no, go to compliance statements.*** ***Inspector should view logs and current status (while observing compounding) to verify.*** ***If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.***	Yes		4.2.1, 4.2.5, 5
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. ***Inspector should review a graphic of the airflow contained in the certification report.***	Yes		4.2.1, 4.2.5, 5
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). ***Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.***	Yes		4.2.1, 4.2.5, 5
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. ***Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.***	Yes		4.2.1, 4.2.5, 5

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		Observation	Inspector Notes	USP Reference(s)
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. ***Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.*** ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).***	Yes		4.2.1, 4.2.5, 5
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. ***If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).***	Yes		4.2.1, 4.2.5, 5
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, 5
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (outside of anticipated variations due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, 5
26.0	Are pressure differential monitoring procedures in place that include an alarm or alert when there is an excursion? ***Inspector note: USP <797> does not require there to be an alarm or an alert.***	Yes		4.2.5

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Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
27.0	Does the facility perform both sterile and nonsterile compounding?	No	Only sterile compounding is performed.	4.2.1
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	N/A		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.*** ***If no, go to compliance statements.*** ***If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.***	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	N/A		4.2.1
29.3	PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification air quality during nonsterile compounding.	N/A		4.2.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? ***Inspector note: Category 1 CSPs can be made from nonsterile components.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.1, 4.2.6
31.0	Does the pharmacy's presterilization procedures comply with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.***	Yes		4.2.6
31.1	Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). ***Inspector note: This statement only applies for Category 2 and Category 3.***	Yes		4.2.6
31.2	Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination. ***Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for presterilization procedures must be certified at least every six months.***	Yes		4.2.6

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		Observation	Inspector Notes	USP Reference(s)
	Certification and Environmental Monitoring Inspector to review past two (2) Certification reports for the SEC and all PECs.			5
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***Inspector is to review current certification reports.***	Yes		5
32.1	The most recent PEC and SEC certification reports are available for review.	Yes		4.2, 5, 20
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes	Last certified on 5/9/2025.	4.2.3, 5
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. ***Inspector note: Classified areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality.***	Yes		5
32.4	Certification reports are reviewed by the designated person(s). ***Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.***	Yes		4.2, 5

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		Observation	Inspector Notes	USP Reference(s)
32.5	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, pharmaceutical isolators, IVLFZ, and robotic enclosures) have been certified within the last six months. ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.2.3, 5
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. ***Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.*** ***If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).***	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last six months. ***Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.*** ***If no, record the date of the last certification and include a copy of the certification report with the inspection report.***	Yes		4.1.1, 4.1.2, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
32.8	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. ***If no, describe what occurred and the pharmacy's response (eg, pharmacy reduced BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).***	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? ***Inspector note: It is recommended that the designated person review the certification report in its entirety.*** ***If no, go to compliance statements.***	Yes		5, 20
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). ***Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all impaction air samplers must be serviced and calibrated as recommended by the manufacturer."***	Yes		5.1, 6.1, 20
33.2	The certification report includes the name of the certifier. ***Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.3	The certification report describes the "dynamic conditions" including the number of personnel in the cleanroom suite. ***Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.***	Yes		5, 20
33.4	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **air volume and room air exchange rate (ACPH).** ***Inspector note: Per USP <797>, unclassified SCAs have no ACPH requirement.*** ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5 Table 6
33.5	**SEC:** All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. ***If pharmacy only compounds in an SCA, inspector should answer statement as N/A.***	Yes		4.2.4, 5
33.6	**The ISO Class 8 anteroom** is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. ***If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.***	Yes		4.2.4, 5 Table 6

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		Observation	Inspector Notes	USP Reference(s)
33.7	**The ISO Class 7 buffer room and ISO Class 7 anteroom (if required)** is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. ***Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.***	Yes		4.2.4, 5 Table 6
33.8	**SEC: Airflow testing** is performed and documented on the certification report to determine acceptability of the **room pressure differential** in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	**SEC:** The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. ***Inspector note: No pressure differential is required between the SCA and the surrounding area.***	Yes		4.2.1, 4.2.5, 5
33.10	**SEC:** All SEC HEPA filters were leak tested (to confirm **HEPA filter integrity**).	Yes		5
33.11	**SEC:** All SEC HEPA filters with leaks were repaired. ***If leaks were not repaired, describe what actions pharmacy took (eg, pharmacy implemented mitigation strategies such as reduced BUD or used alternative pharmacy location).*** ***If no repairs were needed, inspector should answer statement as N/A.***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
33.12	**PEC: (Dynamic airflow) Smoke pattern tests** are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. ***Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."*** ***Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.***	Yes	Smoke pattern testing was thoroughly documented in the report.	4.2.2, 4.2.3, 5
33.13	**PEC: Dynamic airflow smoke pattern** confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. ***Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."***	Yes		4.2.2, 4.2.3, 4.5, 5, 9.1
33.14	**PEC: Total (nonviable) particle count** testing was performed under dynamic operating conditions using calibrated electronic equipment. ***Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."***	Yes		5, 5.1

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		Observation	Inspector Notes	USP Reference(s)
33.15	**PEC:** All PEC HEPA filters were leak tested (to confirm **HEPA filter integrity**). ***Inspector note: The certification report for each PEC should show air velocities within the PEC.***	Yes		5
33.16	**PEC:** All PEC HEPA filters with leaks identified were repaired. ***If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).*** ***If no repairs were needed, inspector should answer statement as N/A.***	N/A		5
33.17	**PEC-IVLFZ**: Pharmacy's integrated vertical laminar flow zone (IVLFZ) meets design, functional requirements, and certification requirements under USP <797>. ***Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."*** ***If pharmacy does not use an IVLFZ, Inspector should answer statement as N/A.***	N/A		4.2.3

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		Observation	Inspector Notes	USP Reference(s)
33.18	If a **robotic enclosure is used as the PEC**, or placed within the PEC, a dynamic airflow smoke pattern test must be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the direct compounding area(s). ***If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.***	N/A		4.2.3
34.0	Was smoke testing performed in SEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? ***Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, or equipment has been moved within SEC since last certification.***	N/A		5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? ***Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."*** ***If no, go to compliance statements.***	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area, ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		6, 6.1, 6.2
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		6, 6.1, 6.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		6, 6.1, 6.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		6, 6.1, 6.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		6, 6.1, 6.2

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		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. ***Inspector note: Per USP, the program is reviewed to "assess risks for contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."***	Yes		6, 6.1, 6.2, 20 Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and procedures for air sampling and surface testing. ***If sampling is conducted by internal personnel, Inspector should verify that documented training and competencies are located in the employee file.***	Yes		6, 6.1, 6.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		6, 20
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected (to obtain a sample that is representative of the typical compounding conditions at the pharmacy)? ***Inspector note: this is a USP recommendation.***	Yes		6.1, 6.3

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		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy send out all air quality for viable airborne samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	Yes	Every 6 months.	6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? ***If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.***	N/A	All surface sampling is performed at the pharmacy and air sampling is sent out to independent lab.	6.3
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters meet USP <797> requirements (eg, the correct temperature and the correct length of incubation time are documented in the report)? ***Inspector note: Incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.*** ***This question applies for any air or surface sample sent to an external lab. If no, describe observations.***	Yes		6.2.2
40.0	Are processes for sampling and monitoring **air quality for viable airborne** particles in compliance with USP <797> standards? ***Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.*** ***Review six months of air sampling data to verify. If no, go to compliance statements.***	Yes		6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (impaction air sampler). ***Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).***	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the **frequencies** specified by USP for volumetric active air sampling. ***Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.*** ***For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.***	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.2 Box 5
40.4	All impaction air samplers are serviced and calibrated as recommended by the manufacturer.	Yes		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.***	Yes		6.2.2 Box 5

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		Observation	Inspector Notes	USP Reference(s)
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C–25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 5
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797> (Box 5), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). **ISO Class 5: >1 cfu/m^3/device** **ISO Class 7: >10 cfu/m^3/device** **ISO Class 8: > 100 cfu/m^3/device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media separately.***	Yes		6.2.3 Table 7

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Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring **surfaces for viable particles** in compliance with USP <797> standards? ***Review six months of surface sampling data to verify. If no, go to compliance statements.***	Yes		6.3
41.1	**Surfaces** and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. ***Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.***	Yes		6.3, 6.3.1

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		Observation	Inspector Notes	USP Reference(s)
41.2	**Surfaces** within the cleanroom suite and SCA are sampled at the **frequencies** specified by USP for viable particle surface sampling. ***Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.*** ***Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used. If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.*** ***For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.***	Yes		6.3, 6.3.1, 14.4.2
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. ***Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contain general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."***	Yes		6.3.2 Box 6

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		Observation	Inspector Notes	USP Reference(s)
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. ***Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	Yes		6.3.2 Box 6
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. ***Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.*** ***If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.***	N/A		6.3.2 Box 7

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		Observation	Inspector Notes	USP Reference(s)
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). **ISO Class 5: >3 cfu/media device** **ISO Class 7: >5 cfu/media device** **ISO Class 8: > 50 cfu/media device** ***Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.***	Yes		6.3.3 Table 8
41.7	For any surface sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. ***Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).***	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine cause, and a corrective action plan is implemented.	Yes		6.3.3

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personal Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment to the designated person(s). ***Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections.***	Yes		3, 3.1
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. ***Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.***	Yes		3, 3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	Yes		3.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anterooms, buffer rooms, or segregated compounding areas.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy stock the necessary garb to ensure minimum garbing requirements are continuously met in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
43.1	The pharmacy stocks gowns and/or coveralls that are low-lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		3.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		3.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		3.3
43.4	The pharmacy stocks facial hair covers (not masks) that are low-lint. ***If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.***	Yes		3.3
43.5	The pharmacy stocks masks that are low lint.	Yes		3.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		3.3
43.7	**Category 1 and Category 2:** All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. ***If only disposable items are used, inspector should mark as N/A.***	N/A	Only use disposable garb.	3.3

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		Observation	Inspector Notes	USP Reference(s)
43.8	**Category 3 only:** The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2
43.9	**Category 3 only:** The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). ***Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.***	N/A		3.3
43.10	**Category 3 only:** All non-disposable garb used to prepare Category 3 CSPs is **laundered and resterilized** with a validated cycle before each use. ***Document whether laundering and sterilization is performed in-house or by an outside vendor.*** ***If only disposable items are used, inspector should answer statement as N/A.***	N/A		3.3, 14.4.2

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		Observation	Inspector Notes	USP Reference(s)
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? ***Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."*** ***If no, go to compliance statements.***	Yes		2.3
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or SCA.	Yes		2.3
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? ***Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find this information documented on a training/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).***	Yes		2.3, 20

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		Observation	Inspector Notes	USP Reference(s)
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		2.3
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3

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		Observation	Inspector Notes	USP Reference(s)
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. ***Inspector note: Media is to be inoculated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed before the expiration date).*** ***If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.***	Yes		2.3
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. ***If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.***	N/A		2.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% nonsterile solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control container. ***If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.***	N/A		Box 2

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Disinfection			7
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? ***If no, go to compliance statements.***	Yes		7, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used within PEC).	Yes		7.1.2
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the classified areas or SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners **EPA-registered disinfecting agent(s)** to adequately perform cleaning and disinfection. ***Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label. Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.***	Yes	Peridox	7.1.1 Box 7 <1072>

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		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate **EPA-registered sporicidal agent(s)** to adequately perform sporicidal disinfection. ***Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.*** ***Compounding personnel should have access to SDS and information/knowledge on dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*** ***Per USP, inspector should check to see if agent is effective against Clostridium difficile.***	Yes	Peridox	7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. ***Inspector should verify that no expired agents are present.***	Yes		7.1.1
46.7	When used in the PEC, any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. ***If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.***	N/A		7.1.1 –
47.0	Does the pharmacy's documented **cleaning and disinfection** activities for surfaces in the classified areas and/or SCA comply with the **frequencies** specified in USP <797> Table 10? ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2 Table 10
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. ***If the PEC is not equipped with a removeable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. ***If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. ***Inspector note: Equipment in the SEC/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.***	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. ***If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.***	Yes		7.2 Table 10
47.13	Ceilings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. ***If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.***	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
48.0	Does the pharmacy's documented application of **sporicidal disinfectant** on surfaces comply with the **frequencies** specified for each CSP category in USP <797> Table 10? ***Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.*** ***Review cleaning logs to verify. If no, go to compliance statements.***	Yes		7.2, 14.4.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.1	**Sporicidal disinfectant** is applied to all interior surfaces of the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg, counters, work tables) at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.***	Yes		7.2 Table 10
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*** ***If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.***	N/A		7.2 Table 10

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
485	Sporicidal disinfectant is applied to the floors in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.***	Yes		7.2 Table 10
486	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
487	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
488	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		7.2 Table 10
489	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. ***Inspector note: Per USP <797>, Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.***	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.***	Yes		4.4, 7.2 Table 10
48.11	Sporicidal disinfectant is applied to the work surface of the removable tray in the PEC and area underneath the removable work tray at least monthly. ***Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*** ***If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.***	N/A		7.2 Table 10
	Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relebelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			9
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? ***Inspector note: Per USP <797>, non-API components may include pharmaceutical excipients, sterile containers, and container closure systems.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? ***Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If no, go to compliance statements.*** ***If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.***	Yes		9.3

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		Observation	Inspector Notes	USP Reference(s)
50.1	**APIs**: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. ***If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.***	Yes		9.3.1
50.2	**APIs:** All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	**APIs:** All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Yes		9.3.1
50.4	All **non-API components** comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All **non-API components** are accompanied by documentation (eg, COA, labeling) that include the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1

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		Observation	Inspector Notes	USP Reference(s)
50.6	All **non-API components** used are manufactured by an FDA-registered facility. ***Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an acceptable and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspections, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."***	Yes		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? ***Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.*** ***If no, go to compliance statements.*** ***If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.***	Yes		9.3.2, 9.3.3
51.1	APIs or other components have been evaluated for use in sterile drug preparation. ***Inspector note: Per USP <797>, "Components labeled with 'not for pharmaceutical use,' 'not for injectable use,' 'not for human use' or an equivalent statement must not be used to compound for these purposes."*** ***If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.***	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other aspects of unacceptable quality (eg, outer packaging is damaged, temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and container-closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	Yes		9.3.2, 9.3.3
51.5	All components are reinspected before use. ***Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures are visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.***	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Supplies			9
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparation. ***Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).***	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. ***Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.***	Yes		9.1

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		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, non-sterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. Per USP, "Injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs." ***If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.***	Yes		9.1, 9.3.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? ***If no, go to compliance statements.***	Yes		9.1, 20
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4
53.2	Automated compounding devices (ACDs) and other similar equipment (single channel or multi-channel) are assessed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. ***Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measures. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."***	Yes		9.1

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		Observation	Inspector Notes	USP Reference(s)
53.3	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. ***If the pharmacy does not incubate samples and or/media-fills in-house, inspector should answer statement as N/A.***	Yes		6.1, 6.2.2, 6.3.2
53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. ***Inspector note: Incubators store media at 20°C-25°C and 30°C-35°C. If the pharmacy has more than one incubator, review records for both incubators.*** ***View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.***	Yes	Records reviewed.	6.2.2, 6.3.2 Box 5
	Compounding Personnel Observation - Inspector ***must*** observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. If the inspector is unable to view activities from a window or other observation area, it is expected they will gown/garb into compounding area. It is acceptable for pharmacy staff to perform mock compounding activities (with sterile saline or other drug) as long as all observations can be viewed.			
54.0	**Personnel Preparation Observation:** Before entering the compounding area, do compounding personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.1
54.1	All outer garments such as hats, scarves, sweaters, bandanas, vests, coats, and jackets are removed.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
54.2	Makeup and/or cosmetics are removed.	Yes		3.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		3.1
54.4	Earbuds or headphones are removed.	Yes		3.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		3.1
54.6	Nails are kept clean and neatly trimmed.	Yes		3.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		3.1
54.8	If worn, eyeglasses are wiped. ***If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.***	Yes	Pharmacy has glass cleaner wipes.	3.1
54.9	Any accommodations permitted by the designated person(s) have been documented. ***Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
55.0	**Hand Hygiene Observation:** Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		3.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2 Box 3
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). ***Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.***	Yes		3.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		3.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. ***Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).***	Yes		3.2 Box 3

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		Observation	Inspector Notes	USP Reference(s)
55.6	Soap containers are not refilled or topped off.	Yes		3.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		3.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes		3.2 Box 3
56.0	**Garbing Observation:** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. ***Inspector note: Per USP <797>, additional garbing requirements must be continuously met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.***	Yes		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. ***Inspector note: USP recommends (not requires) the donning procedure to be performed in the anteroom.*** ***If no, inspector must describe in the notes column why a risk of contamination is a concern.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.4	Doffing procedures are performed in an order that reduces the risk of contamination.	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.***	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a classified room or SCA. ***Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #97.***	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
56.9	**Category 1 and Category 2 only:** Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. ***Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately. If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.***	Yes		3.3
56.10	**Category 1 and Category 2 only:** Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. ***Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing). If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.***	Yes		3.3
57.0	List the name(s) of the CSPs observed by the inspector as part of live compounding demonstration.		Semaglutide 2mg/ml with Cyanocobalamin 180mcg/ml 3ml vials	
58.0	**Compounding Observation:** Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		1, 2.1, 2.3

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		Observation	Inspector Notes	USP Reference(s)
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. ***If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.***	Yes		4.1.2
58.2	**Category 2 and Category 3 only:** All PECs are placed in a cleanroom suite. ***Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA."*** ***If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.***	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the anteroom, placed into a pass-through chamber, and/or brought into the SCA. ***Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant dwell time minimums, as specified by the manufacturer, are to be followed.***	Yes		8.1

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		Observation	Inspector Notes	USP Reference(s)
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use. ***Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."***	Yes		8.2
58.6	Aseptic processes and manipulations are performed in a manner intended to minimize the risk of contamination. ***Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination on the plunger rod); proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.***	Yes		2.3
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag septums) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. ***Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC. This may not occur when compounder is staging the next batch.***	Yes		3.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? ***Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.***	Yes		15
59.1	Single dose containers (entered or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "This time limit for entering or puncturing (a single-dose CSP or CSP stock solution) is not intended to restrict the BUD of the final CSP."***	Yes		15.1, 16.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. ***Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).***	N/A		14.5, 15.2, 16.1

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		Observation	Inspector Notes	USP Reference(s)
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. ***Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.***	Yes		15.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. ***Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.***	Yes		15.3
60.0	**Inspect several different finished compounded sterile preparations.** Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
61.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates).*** ***These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.***	Yes		2 Table 2, Table 3
62.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? ***If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only."*** ***If no, go to compliance statements.***	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes		7.1.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. ***Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."***	Yes		7.1.1, 7.1.2
62.6	Only sterile supplies and equipment are permitted for use in the PEC. ***Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.***	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1

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		Observation	Inspector Notes	USP Reference(s)
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. ***Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.***	Yes		7.1.2 Box 7, Box 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. ***Per USP, contact times should be included in the SOP based on the agent used.***	Yes		7.1.1 Box 7, Box 8
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. ***Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.***	Yes		7

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		Observation	Inspector Notes	USP Reference(s)
	Sterilization and Depyrogenation			10
63.0	Does the pharmacy compound preparations with any nonsterile starting components? ***If the pharmacy does not compound preparations with any nonsterile starting components, inspector should answer question as N/A.***	Yes		10
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? ***If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.*** ***If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.***	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***View compounding records for CSPs sterilized by filtration to verify.*** ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	Yes		10.2 USP <1229.4>

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		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. ***Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."***	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Inspector note: Per USP <797>, sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used. "Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."	Yes		10.2
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. ***Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.*** ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2

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		Observation	Inspector Notes	USP Reference(s)
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. ***Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.***	Yes		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. ***If no, collect a copy of the master formulation record and compounding record.***	Yes		10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2
66.0	**Steam Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.*** ***View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.3 USP <1229.1>

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		Observation	Inspector Notes	USP Reference(s)
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. ***Inspector note: Per USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam heat.***	N/A		10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	N/A		10.3
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. ***Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.***	N/A		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	N/A		10.3

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		Observation	Inspector Notes	USP Reference(s)
66.6	The appropriate biological indicators (USP <1229>) are used to verify the effectiveness of each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see Physicochemical Integrators and Indicators for Sterilization USP <1229.9>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."***	N/A		10.3 USP <1229.5> USP <1229.9>
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. ***Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 20-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).*** ***Any parameters for the autoclave must be set through validation.***	N/A		10.3 USP <1229.1>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	N/A		10.3, 20

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		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? ***Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1229.8> also applies.*** ***View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.*** ***If the pharmacy does not use this sterilization method, inspector should answer question as N/A.***	N/A		10.4 USP <1229.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. ***Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be able to get to the appropriate temperature and pressure, for example, not be a toaster oven.***	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 160°C or higher. ***Inspector note: Per USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.***	N/A		10.4

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		Observation	Inspector Notes	USP Reference(s)
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. ***Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.5>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."***	N/A		10.4 USP <1229.5>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20
68.0	**Dry Heat Depyrogenation:** Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? ***View documentation records of items depyrogenated to confirm.*** ***If the pharmacy does not use this method, inspector should answer question as N/A.***	Yes		10.1 USP <1228.1>
68.1	Glassware, metal, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	Yes		10.1

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		Observation	Inspector Notes	USP Reference(s)
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. ***Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.***	Yes		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. ***Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.***	Yes		10.1 USP <1228.4>
	Master Formulation and Compounding Records **Inspector should review a minimum of five (5) master formulation records and five (5) compounding records.**			11
69.0	Are **Master Formulation Records (MFRs)** created and maintained in compliance with USP <797> standards? ***If no, go to the compliance statements.***	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20

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69.4	The MFR includes the name, strength or activity, and dosage form of the sterile compounded preparation.	Yes		11.1, 20
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 20
69.13	The MFR includes all required release tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 20
70.0	Are **Compounding Records (CR)** created and maintained in compliance with USP <797> standards? ***Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.*** ***If no, go to compliance statements.***	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all for immediate-use CSPs prepared for more than one patient. ***Inspector note: If pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.***	Yes		11.2 Box 10
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10

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National Association of Boards of Pharmacy®
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Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
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		Observation	Inspector Notes	USP Reference(s)
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, prescription, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. ***Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).***	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10

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		Observation	Inspector Notes	USP Reference(s)
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. ***Inspector note: Per USP, "If applicable, the CR must also include...Calculations."***	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with in-process and final checks. ***Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."***	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? ***If no, go to compliance statements.***	Yes		13 USP <7>

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		Observation	Inspector Notes	USP Reference(s)
71.1	Information on the label is prominently and legibly displayed. ***Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed." The shipping container is not included in the definition of the "label."***	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13

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		Observation	Inspector Notes	USP Reference(s)
71.9	Labeling on the immediate container includes the total amount or volume when not obvious from the container.	Yes		13
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be sent outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? ***Inspector note: Per USP, this is a recommendation/should.***	Yes		13 USP <7>

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		Observation	Inspector Notes	USP Reference(s)
	Establishing BUDs			14
73.0	**Category 1 and Category 2 CSPs:** Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that its packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	**Category 1 CSPs:** BUDs for **Category 1 CSPs** prepared in an SCA do not exceed the limits established in Table 12. ***Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C). If no Category 1 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, Table 12

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		Observation	Inspector Notes	USP Reference(s)
73.4	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using one or more nonsterile starting components are defined as: one day CRT; four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using only sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, Table 13
73.5	**Category 2 CSPs:** BUDs for **aseptically processed (by filtration) Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer.*** ***If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.***	Yes		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
73.6	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** that **do not** undergo sterility testing do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to probability of nonsterile unit (PNSU) of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.*** ***If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, Table 13
73.7	**Category 2 CSPs:** BUDs for **terminally sterilized Category 2 CSPs** where **sterility testing and endotoxin testing (if applicable) are performed** and passed do not exceed the limits established in Table 13. ***Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized to PNSU of 10^{-6} (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.*** ***USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.*** ***If no terminally sterilized Category 2 CSPs are prepared, Inspector should answer statement as N/A.***	N/A		14.3, 14.2.1, 14.2.3, Table 13

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		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? ***Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur: formula within a formula, preservative-free compounded component used in a preserved final CSP, "in-use" times for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		14.3
75.0	Are BUDs for **Category 3 CSPs** assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? ***Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.***	N/A		14.3, 14.4., 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for **Category 3 CSPs** do not exceed the maximum limits for aseptically processed (eg, filtered) established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.***	N/A		14.4.1 Table 14
75.4	BUDs for **Category 3 CSPs** do not exceed the maximum limits for terminally sterilized established in Table 14. ***Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 90 days CRT; 120 days refrigerator; and 180 days frozen.***	N/A		14.4.1 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.5	**Category 3 CSPs** are supported by stability data obtained using methods described in USP <1225> or a validated noninferior stability-indicating analytical method. ***Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.*** ***View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.***	N/A		14.4.3 Table 14 USP <1225>
75.6	**Category 3 CSPs** undergo sterility testing. ***Inspector note: Sterility testing is performed on all Category 3 CSPs.***	N/A		14.4.4 Table 14 USP <71>
75.7	**Category 3 CSPs** undergo bacterial endotoxin testing. ***If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.***	N/A		12.3, 14.4.4 Table 14 USP <85>
75.8	**Category 3 CSPs** undergo particulate matter testing. ***Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).***	N/A		14.4.3 Table 14 USP <788>, <789>

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		Observation	Inspector Notes	USP Reference(s)
75.9	**Category 3 CSPs** undergo an evaluation for the container closure system. ***Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation— Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.***	N/A		14.4.3 Table 14 USP <1207>
76.0	Are **multiple-dose CSPs prepared** in compliance with USP <797> standards? ***If no, go to compliance statements.*** ***If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.***	Yes		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."	Yes		14.5

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		Observation	Inspector Notes	USP Reference(s)
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. ***Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature,, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study. Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.***	Yes		14.5 USP <51>
76.4	Multiple-dose CSPs are labeled to indicate the beyond use date of the CSP once it is opened or punctured. ***Inspector note: Labeling on the CSP should indicate that once the CSP container is entered or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.*** ***Inspector should review the CR or final compounded preparation to verify the label contains this information.***	Yes	Verified.	14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. ***Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.***	Yes		14.5 USP <1207>

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		Observation	Inspector Notes	USP Reference(s)
	Finished Preparation Release Checks and Tests			12
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		12.1
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? ***Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.***	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <71> and USP <797>, are tested. ***Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:*** ***Parenterals*** ***Not more than 100 containers = 10% or four containers, whichever is greater*** ***More than 100, but not more than 250 containers = 10 containers*** ***Large volume parenterals*** ***2% or 10 containers, whichever is less*** ***Non-parenterals (eye drops, inhalation, pellets, etc.)*** ***Not more than 200 containers = 5% or two containers, whichever is greater*** ***More than 200, but not more than 250 containers = 10 containers*** ***Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:*** ****If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number.*** ****If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used.***	Yes		12.2, 14.2.3 USP <71>
78.2	Batch sizes of sterile CSPs do not exceed 250. ***Inspector Note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.***	Yes		12.2, 14.2.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). ***Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."*** ***If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.***	N/A		12.2 USP <71>, <1223>
78.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. ***Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented." Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.***	Yes		12.2

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Facility Name: Cubance, LLC dba Source Pharmacy
e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require **bacterial endotoxin testing**, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? ***Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described in USP Chapter <85> for the route of administration for humans, and for animals based on weight.*** ***Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.*** ***If no, go to compliance statements.*** ***If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.***	Yes		12.3 USP <85>
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. ***Per USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.*** ***If the dosage form does not require, inspector should answer statement as N/A.***	Yes		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. ***If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.***	N/A	No veterinary compounding.	12.3

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Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
79.3	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 2 CSPs** compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. ***Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.***	Yes		12.3 Table 13 USP <85>
79.4	Bacterial endotoxins testing (USP <85>) is performed on all **injectable Category 3 CSPs** compounded from one or more nonsterile components.	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. ***View testing records and note any products with failed results and actions taken.***	Yes	No endotoxin testing failures.	12.2, 12.3
	CSP Packaging, Shipping and Transport			**19**
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2

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e-Profile ID: 1889423
Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. ***Inspector should look at packaging materials used to ensure cushioning to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.***	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). ***Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.***	Yes		19.3
	Quality Assurance and Quality Control			**18**
81.0	**Quality Assurance and Quality Control (QA/QC):** Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes		18 USP <1163>
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2

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		Observation	Inspector Notes	USP Reference(s)
81.2	**QA/QC Out-Of-Specification (OOS) SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1
81.6	**QA/QC OOS SOPs:** The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? ***If no, go to compliance statements.***	Yes	Had one complaint about a vial.	18, 20

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		Observation	Inspector Notes	USP Reference(s)
82.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system of: adherence to procedures; prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."***	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20
82.4	All complaints and adverse events are thoroughly investigated. ***Inspector note: Per USP <797>, the timeframe is specified in the facility SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs."*** ***If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state.***	Yes		18.2, 18.3, 20

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		Observation	Inspector Notes	USP Reference(s)
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. ***Inspector note: Per USP <797>, the complaint record must contain the following information:*** ***-Name of the complainant or other unique identifier;*** ***-Date the complaint was received;*** ***-Nature of the complaint;*** ***-The response to the complaint; and*** ***-Results of any investigation and any follow-up.*** ***In addition, to the extent that the information is known, the following should be recorded:*** ***-The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number).*** ***If no, inspector should document what is missing in the notes column.***	Yes		18.2, 20
82.6	The pharmacy's QA/QC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. ***Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."***	Yes		18.1, 18.2

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		Observation	Inspector Notes	USP Reference(s)
83.0	If a CSP is dispensed or administered **before the results of release testing are known**, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? ***Inspector note: Per USP <797>, if a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.*** ***If no, go to the compliance statements.***	N/A		18.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	N/A		18.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	N/A		18.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	N/A		18.1

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Inspection Date: 09/22/2025, 09/24/2025 & 09/25/2025

		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation - Verify records of all compounding personnel (up to 10). **Use the records tab to document records reviewed.**			2
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluations compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.2, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? ***Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.*** ***If no, refer to the records review worksheet for details.***	Yes		2, 2.1, 17 Table 2, Table 3

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Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file.
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound (Note: frequency of competency assessment will be defined by pharmacy SOPs).
Review five (5) personnel files and document your observations. (For applicants seeking a Class E-S Non-Resident Sterile Compounding inspection (Texas Sampling), review a total of 10 personnel records.)
- *Note: long-term employees may not have initial training available, if this is the case, you may select an alternative file. If an alternate file is not available, document length of service of long-term employee.
Inspector Note: soybean casein digest medium and trypticase soy broth are the same media.

Inspector Instructions	Demonstrating Knowledge and Competency of Core Skills (Section 2.1)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1. Personnel who perform or oversee compounding *or support activities* must be trained in the SOPs and trained on maintaining the quality of the environment (See Table 2). 2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions (See Table 2 and Table 3). This must be completed initially and every 12 months in at least the following areas: -Hand hygiene -Garbing -Cleaning and disinfection -Calculations, measuring, and mixing -Aseptic technique -Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components) -Use of equipment -Documentation of the compounding process (eg, master formulation and compounding records) -Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area -Proper use of PECs -Principles of movement of materials and personnel within the compounding area 3. Personnel who only perform restocking or cleaning and disinfecting duties outside of the primary engineering control (PEC) must complete ongoing training as required by the facility's SOPs (See Table 3). 4. Personnel compounding only immediate-use CSPs must complete training as required by the facility's SOPs (See Table 3). 5. All training and evaluations must be documented.

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	*Initial Training and Competency in Maintaining the Quality of the Environment	*Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Practices	Notes
				Compounders and Supervising Personnel: Initially and at least every 12 months Other Personnel (examples: persons who do not compound but clean/disinfect and restock or who perform in-process checks; persons who only compound immediate use): Initially and as defined by pharmacy SOPs				
#1	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	Pharmacy has only been open since 3/2025.

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#2	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	Pharmacy has only been open since 3/2025.
#3	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	Yes	Pharmacy has only been open since 3/2025.
#4								
#5								
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions	Hand Hygiene and Garbing Competency Evaluation (Section 2.2)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP requirements: 1. The garbing and hand hygiene competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands. 2. The initial competency evaluation consists of three (3) separate and complete hand hygiene observation, followed by a full garbing procedure and a GFT after garbing. The initial three (3) successful completions must be in succession—failure of any of the three (3) initial garbing competency evaluations requires repeat testing until personnel successfully complete three (3) evaluations in a row. 3. The pharmacy uses a microbiological growth media device (eg, plates, paddles, or slides) containing general microbial growth agar (eg, trypticase soy agar [TSA]) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) that supports both bacterial and fungal growth. 4. The media device is incubated at 30°C-35°C for no less than 48h and then at 20°C-25°C for no less than an additional five days. 5. Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or GFT results that exceed the defined action levels. Action level after garbing: >0 cfu/total from both hands. 6. Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (the number of cfu per hand must be recorded; microbial identification of the cfu is not required by the chapter for GFT) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Hand Hygiene and Garbing Visual Observation	*Initial GFT x 3 (Post hand washing and garbing)	Subsequent GFT (Post handwashing and garbing)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: initially and at least every 6 months Category 3 compounders: initially at least every 3 months Supervising Personnel: initially and at least every 12 months				
#1	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#2	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	N/A	
#3	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	N/A	
#4								
#5								
#6								
#7								
#8								
#9								
#10								

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Inspector Instructions	Aseptic Manipulation Competency (Section 2.3)
1. Use the drop-down list and make the appropriate selection for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the title or position. 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and demonstrated competency. 3. Select the appropriate response for each item reviewed. -Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. -Select "No" if the document is present but is not compliant with USP <797> standards (eg, incorrect frequency of test, GFT and surface sample was not conducted after media-fill, failed tests did not include a corrective action, etc). Document the area(s) of non-compliance in the notes column. -Select "Missing" if the document is not present in the file. -Select "N/A" if the training does not apply, eg, long-term employees may not have initial training available. Document further in the notes column. 4. Use the notes column to document any pertinent information. 5. Document in notes if initial aseptic manipulation competencies are present in files (*unless long-term employee).	USP requirements: 1. Media-fill testing procedures simulate the most difficult compounding procedures encountered by personnel. 2. The pharmacy conducts media-fill testing as described in Box 2. 3. The final containers are incubated at 20°C-25°C and 30°C-35°C for a minimum of seven days at each temperature band. 4. Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container closure unit(s) on or before 14 days. 5. Immediately following the media-fill test, GFT is performed on both hands and inside of an ISO Class 5 PEC. Failure is indicated by visual observation of GFT results that exceed defined action levels. Action level after media-fill testing: >3 cfu/total from both hands. 6. Immediately following the GFT, a surface sample of the direct compounding area inside the PEC is performed in accordance with USP standards for surface sample monitoring and action levels. Action level ISO Class 5: >3 cfu/media device. 7. Failure in the media fill, GFT, or surface sampling constitutes an overall failure of the aseptic manipulation competency. 8. Documentation includes, at minimum: -Name of the person evaluated -Evaluation date and time -Media and components used including manufacturer, expiration date, and lot number -Starting temperature for each interval of incubation -Dates of incubation -Results (for GFT, the number of cfu per hand must be recorded and for surface samples, the number of cfu per sample must be recorded. Note: microbial identification of the cfu is not required for media-fill testing) -Results of the evaluation and any corrective actions -Name of the observer and personnel reading and documenting the results

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Aseptic Manipulation Visual Observation	Media-fill	GFT (post media-fill)	Surface Sampling (post media-fill)	Documented Failures and Retraining Needs (If none, please mark as N/A)	Notes
				Category 1 and 2 compounders: initially and at least every 6 months Category 3 compounders: initially and at least every 3 months Supervising Personnel: initially and at least every 12 months					
#1	Pharmacy Technician	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#2	Pharmacist	Designated Person	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#3	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	Yes	N/A	
#4									
#5									
#6									
#7									
#8									
#9									
#10									

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GLOSSARY USP <797>
ACD: Automated compounding device.
ACPH: Air changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *Bulk drug substance*. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient.*
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription sets.
Allergenic extract prescription set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.

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Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at an irreducible minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood components: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient.*

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Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.
Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class).*
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the SCA, or AECA).

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Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.
Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions).* This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study).*

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Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).
ECV: Endotoxin challenge vial.
EPA: US Environmental Protection Agency.
Excipient: See the entry for *Added substance.*
FDA: US Food and Drug Administration.
Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.
Final yield: The total number of containers prepared at the end of the compounding process prior to release testing.
First air: The air exiting the HEPA filter in a unidirectional air stream.
Formulation: The specific qualitative and quantitative composition of the final CSP.
Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).
GFT: Gloved fingertip and thumb testing.
Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.
High-efficiency particulate air (HEPA) filtration: Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.
HVAC: Heating, ventilation, and air conditioning.
Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worktables and by effective placement of air returns.
IPA: Isopropyl alcohol.

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ISO class: An air-quality classification from the International Organization for Standardization.
ISO: International Organization for Standardization.
Label: The part of the labeling on the immediate container.
Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except any outer shipping container.
Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.
Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.
Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.
Low-lint wiper: A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.
Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.
MEA: Malt extract agar.
Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.
Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.
One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

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Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available for consultation if and when needed, even if not physically present.
Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.
Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]
Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package.*
Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.
PPE: Personal protective equipment.
Preservative: A substance added to inhibit microbial growth.
Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.
Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]
Pyrogen: A substance that induces a febrile reaction in a patient.
Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.
Reconstitution: The process of adding a diluent to a conventionally manufactured product to prepare a sterile solution or suspension.
Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

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Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.
Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
SDA: Sabouraud dextrose agar.
Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.
Single-dose containers: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.
SOP: Standard operating procedure.
Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.
Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Sterility assurance level (SAL): See the entry for *Probability of a nonsterile unit* (PNSU).
Sterility: The absence of viable microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.

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Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-µm pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10−6 or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology comprised of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.) * Current license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☑ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: FA6102278 ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Affordable RX, INC / dba Affordable Script

Physical Address: 179 Rockaway Ave., 2nd Floor

City: Valley Stream State: NY Zip: 11580

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 516-561-6480 Toll Free # (NAC 639.708, NRS 639.23286): 800-325-7995

Fax: 516-561-6483 Contact Email: info@affordablescript.com

Website: www.affordablescript.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Alberto Lopez

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19694

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Alberto Lopez	NV Pharmacist Registration #: 19694
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): Hometech Advanced Therapies, Inc

Corporation/Organization Name: Affordable RX, Inc

Mailing Address: 177 Rockaway Ave., 2nd Floor

City: Valley Stream State: NY Zip: 11580

Telephone: 484-494-3121 Email: info@affordablescript.com

Contact Person Name: Patti Shannon

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☒ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President-Treasurer-Sec (title) for Affordable RX, Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Robert S Cappa

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1-28-2026

Date

Section 10: Affidavit for Pharmacies MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Robert S Cappa hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President Treasurer Sec (title) for Affordable RX, Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28th day of January, 2026

Notary Public

Joseph Braxton
NOTARY PUBLIC, STATE OF NEW YORK
REGISTRATION NO. 01BR0033363
QUALIFIED IN WESTCHESTER COUNTY
COMMISSION EXPIRES 01/31/2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert S Cappa

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1-28-26

Date

Board Use Only	Date Received: 2/5/26	Amount: 500.00/V# 2116

AFFORDABLE Scripts

177 Rockaway Avenue
Valley Stream, NY 11580

Phone: 516-561-6480
Fax: 516-561-6483

Officer:

President Treasurer Secretary

Robert S Cappa

[redacted]

AFFORDABLE RX, INC.
177 Rockaway Avenue, 2nd Floor
Valley Stream, NY 11580

Board of Directors:

Raymond A. Mirra

[redacted]

Renee Sigloch

[redacted]

Robert S Capna

[redacted]

AFFORDABLE Scripts

177 Rockaway Avenue
Valley Stream, NY 11580

Phone: 516-561-6480
Fax: 516-561-6483

5% and Greater Owners:

Hometech Advanced Therapies, Inc.
501 Elmwood Avenue
Sharon Hill, PA 19079
100% Direct Owner of
Affordable RX, Inc

Superior Biologics Holding Company, Inc.
501 Elmwood Avenue
Sharon Hill, PA 19079
100% Direct Owner of
Hometech Advanced Therapies, Inc

EHHC, LLC
501 Elmwood Avenue
Sharon Hill, PA 19079
Tax ID 46-2871318
19% Indirect Owner

ECAG, LLC
501 Elmwood Avenue
Sharon Hill, PA 19079
Tax ID 46-1206692
81% Indirect Owner

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	AFFORDABLE RX, INC.
DOS ID Number:	4929151
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	04/12/2016
Statement Status:	Current
Statement Due Date:	04/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on January 28, 2026 at 08:36 A.M.

WALTER T. MOSLEY
Secretary of State

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100009571286 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Affordable Rx Inc.

Pharmacy/Wholesaler License # (if applicable) NABP - 3338387 NPI 1346283520

Physical Address 177 Rockaway Ave.

City Valley Stream State NY Zip 11580

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 516-561-6480 Website _____

Licensing Company Email affordable script @ yahoo.com

Section 2: Personal Information

First Neil Middle C Last Dubin

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. John's University		09/90 - 05/95	
Address	**City**	**State**	**Zip**
8000 Utopia Parkway	Jamaica	NY	11439
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Hicksville High School		09/87 - 06/90	
Address	**City**	**State**	**Zip**
180 Division Ave.	Hicksville	NY	11801
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05-98 - current	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Affordable Scripts Pharmacy			From - To (MM/YY – MM/YY): 01/25 - current
Business Address: 177 Rockaway Ave.	City: Valley Stream	State: NY	Zip: 11580
Phone: 516-561-6480	Title: Sup. Rph		Number of Employed Hours: 2,000
Description of Duties: Dispensing of medications, provide medical advice maintenance of records, supervisor of staff			

Business Name: Barths Pharmacy			From - To (MM/YY – MM/YY): 10/22 - 12/24
Business Address: 58 Sunset Ave	City: Westhampton Beach	State: NY	Zip: 11978
Phone: 631-288-4345	Title: Rph		Number of Employed Hours: 4,500
Description of Duties: Dispensing of medications, provide medical advice			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Neil Dubin, certify that as the designated representative for Affordable Rx Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ND I am at least 21 years of age;
3. ND I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ND I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ND I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ND I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ND I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Neil Dubin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/30/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Neil Duban

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/3/26

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of NASSAU

I, Neil Duban, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/3/23

Date

Subscribed and Sworn to before me this 03rd day of Feb 2026

Notary Public Signature

AZZAM ELCHEIKH
Notary Public - State of New York
No. 01EL6348428
Qualified in Nassau County
My Commission Expires 09/26/20 28

(Seal)

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1513663		**Inspection Information**
Legal Business Name:	Affordable Rx, Inc	**Conference Call Date:**	11/22/2024
Doing Business As (DBA):	Affordable Script	**Start Time: 24-hour format (13:00)**	13:15
Address:	177 Rockaway Ave	**End Time: 24-hour format (13:00)**	14:25
City:	Valley Stream	**Onsite Inspection Date(s):**	11/26/2024
State:	New York	**Start Time(s): 24-hour format (13:00)**	10:15
Zip Code:	11580	**End Time(s): 24-hour format (13:00)**	12:45
Telephone number:	(516) 561-6480	**Inspector Name(s):**	Cheryl Rashid, RPh
Toll free number:	(800) 325-7995	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	(516) 561-6483	**Observer Name/Affiliation (if applicable):**	na
Website:	www.superiorbiologics.com	**Observer Name/Affiliation (if applicable):**	na

Focused Information

The Focused Items are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As the Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

General Pharmacy: 29.02, 30.00, 47.04, 47.06, 47.07, 47.08, 65.00, 93.06

Additional Information on NABP Inspection Reports

NABP Disclaimer: NABP cannot verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an interested recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open Start Time: (24-hour format)	End Time: (24-hour format)	Closed (X)
Sunday			x
Monday	9:00	16:30	
Tuesday	9:00	16:30	
Wednesday	9:00	16:30	
Thursday	9:00	16:30	
Friday	9:00	16:30	
Saturday			x

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Monte Alan Kravat, Pharm D	montek0722@yahoo.com	647215
Nonsterile Designated person(s)	na	na	na
Sterile Designated person(s)	na	na	na
Hazardous Designated person(s)	na	na	na

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
3	Dr Vincent Nesso	Site Manager for Superior Biologics (Parent Company)	na
1	Monte Alan Kravat, Pharm D	PIC	y
2	Dennis Molloy, RPh	Pharmacist	y
5	Danelle Benitez	Customer Service	na
6	Brenda Heeralall	Customer Service	na
4	Joanne Goodelman	Assistant to PIC	na
7	Marie Leonard	Bookeeper	na
8	Gilsen Merced	Customer Service	na
9			
10			

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Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
New York State Board of Pharmacy	Affordable RX, Inc.	Pharmacy	034684/ exp - 5-31-2025
Drug Enforcement Administration	Affordable RX, Inc	Controlled Substance - Pharmacy	FA6102278/ exp - 6-30-2025

AL, AZ, CO, CT, DE, DC, FL, GA, IL, IN, KY, MN, MO, NJ, NC, OH, PA, RI, SC, SD, VA, WA, WI. The pharmacy does provide CII prescriptions within New York State only. There was no ReliOn Insulin and they use no Market Places.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description

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Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public		Nuclear Pharmacy	
Closed Door	x	Specialty Pharmacy	x
Drive-through window		White bagging/ clear bagging	x
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	x	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	x	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement, and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement, and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	1150	Total Pharmacists:	2
Nonsterile Compounding Room size:	NA	Number of Compounding Pharmacists:	0
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	NA	Total Technicians:	1
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	0	Number of Compounding Technicians:	0
Sterile Compounding Ante Room size:	NA	Of technicians, how many are nationally certified?	0
Sterile Compounding Clean/Buffer Room size:	NA	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	0	Total Other Unlicensed Personnel:	0
Sterile Compounding Number BSC hoods:	0	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	1:1
Sterile Compounding Number CAI/CACI hoods:	0	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	0
Negative Pressure Sterile HD Room size:	NA		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	na
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	na

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	100	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	3%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	0	0	Month
Alaska (AK)			
Arizona (AZ)	1	0	Month
Arkansas (AR)			
California (CA)			
Colorado (CO)	10	0	Month
Connecticut (CT)	17	0	Month
Delaware (DE)	0	0	Month
District of Columbia (DC)	1	0	Month
Florida (FL)	32	0	Month
Georgia (GA)	35	0	Month
Hawaii (HI)			
Idaho (ID)	1	0	Month
Illinois (IL)	13	0	Month
Indiana (IN)	0	0	Month
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)	1	0	Month
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)	1	0	Month
Mississippi (MS)			
Missouri (MO)	17	0	Month
Montana (MT)			

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)	190	0	Month
New Mexico (NM)			
New York (NY)	665	0	Month
North Carolina (NC)	21	0	Month
North Dakota (ND)			
Ohio (OH)	17	0	Month
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)	8	0	Month
Rhode Island (RI)			
South Carolina (SC)	2	0	Month
South Dakota (SD)	0	0	Month
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)	0	0	Month
Washington (WA)	3	0	Month
West Virginia (WV)			
Wisconsin (WI)	1	0	Month
Wyoming (WY)			
Other			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Affordable Rx, Inc dba Affordable Script

e-Profile ID: 1513663

Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	No	Dennis Molloy, RPh
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Dennis Molloy, RPh- Staff Pharmacist; Vincent Nasso, Site Manager. Joanne Goodelman, Administrative Assistant.

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		Observation	Notes
Types of Practice Additional Questions If any part of a question is no, enter "No" and explain the observation.			
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Prolia is sent to MD and labeled with patient name for MD administration. About less than 1 percent of orders.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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		Observation	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	This is a closed door pharmacy though they are displayed in office area.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	Last inspected on 02/14/2016 and are not routinely inspected.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	It was a transfer of ownership with nothing noted as deficient.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	

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		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	7 years
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically on the Cloud and computer system Opus backup.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Prescriptions can be inactivated but not deleted.

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		Observation	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Unknown	
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Corporate will monitor yearly.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Yearly done by Patti Shannon, Licensing and Credentialing Specialist.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	The ratio is 1 to 1. The maximum number of people is seven employees.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Gemini Security monitors the Key punch to enter, fire, and theft
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	No	They are for in state prescriptions only. They are ordered as needed and stored on shelf, not secured separately.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Pharmacist remains on premise.

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		Observation	Notes
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	Pharma Link will pick up as needed.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	They will return to Manufacturer.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	No	
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	Closed door.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	Corporate monitored by CAS Data Logistics with a T & S Data Logger. Any excursions are immediately related to PIC and Site Manager for action. On site today- 72 degrees Fahrenheit and is placed in USP range of 68 to 77 degrees Fahrenheit.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Corporate continuous monitored by CAS Data Logistics with a T & S Data Logger.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	

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Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Corporate monitored by CAS Data Logistics with a T & S Data Logger. Any excursions are immediately related to PIC and Site Manager for action. On site today it was 37 degrees Fahrenheit and is placed in USP range of 36 to 46 degrees Fahrenheit. Records kept for 2 years.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Any excursions are immediately related to PIC and Site Manager for action. On site today- 37 degrees Fahrenheit and is placed in UPS range of 36 to 46 degrees Fahrenheit. Records kept for 2 years.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	Ice packs only.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	No Generator but three refrigerators are available, one kept empty.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Call the Landlord.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	ScriptPro model 200 and Kirby Lester model KL-X are used.
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	Cleaning cycle and alcohol are used per policy.

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		Observation	Notes
Product Receipt and Inventory	**If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	By corporate the Procurement Team.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	McKesson is primary wholesaler.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	No	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	No	

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		Observation	Notes
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	They are kept electronically on site for 6 years.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	PIC has signing authority and forms are secured in a locked space.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	

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53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	They follow a shrink report and there is little inventory, most is ordered in and immediately sent out to patient the next day.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Board of Pharmacy and local law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	Quarterly for Controlled II substances.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	Complete control inventory is done yearly and last done on 8/29/24
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

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59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	N/A	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Pharma Link picks up quarterly.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Monthly
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

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Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
Prescription Processing If any part of a question is no, enter "No" and explain the observation.			
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Pharmacist will enter and customer service updates with each refill.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Most prescriptions are Specialty medications and they will check with MD if a question.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	E Scripts is used as electronic prescription service
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	

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General Pharmacy Inspection

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Facility Name: Affordable Rx, Inc dba Affordable Script

e-Profile ID: 1513663

Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	Opus system has internal DUR update monthly.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Clinical Pharmacology.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Facts and Comparisons may be used.
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Computer system sends daily to states.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	Opus pharmacy system sends daily.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Pharmacist will use their initials.

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Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Opus system will provide.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Prescription is reviewed by three people for accuracy and the final person is the pharmacist with their initials.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Opus Pharmacy System.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Legal Shred.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	

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e-Profile ID: 1513663
Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	N/A	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	N/A	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	No	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	Closed Door.
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	

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e-Profile ID: 1513663

Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Computer printouts and prescription specific material.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	They are added to mailing package.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	They are added to mailing package.

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Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	No	
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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Facility Name: Affordable Rx, Inc dba Affordable Script

e-Profile ID: 1513663

Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
Quality Assurance/Quality Improvement Program	**If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Corporate Quality Team.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronically
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	Amy Boyst, Head of HR and Kelly Coor RPH -Compliance Officer.
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	Formal training on hire and yearly.
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronic

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		Observation	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Corporate Compliance Team.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Open Door policy.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	Uses bar scans for accuracy in product choice and for triple checking contents for deliveries.

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Inspection Date: 11/22/2024 & 11/26/2024

		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Manufacturer, VARES, MedWatch and Board of Pharmacy are all included as warranted.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	Monthly
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2025-28

SUPERVISING PHARMACIST
NEIL DUBON

THIS IS TO CERTIFY

AFFORDABLE RX INC.
177 ROCKAWAY AVENUE
VALLEY STREAM, NY 11580-5823

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF JUNE, 2025.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF MAY, 2028.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
034684

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

2997

AFFORDABLE RX INC.

GENERAL INFO | ENFORCEMENT ACTIONS

Type	Pharmacy
Legal Name	AFFORDABLE RX INC.
Trade Name	AFFORDABLE SCRIPT
Street Address	177 ROCKAWAY AVENUE VALLEY STREAM NY 11580-5823
Registration No	034684
Date First Registered	June 22, 2016
Registration Begins	June 01, 2025
Registered Through	May 31, 2028
Supervisor	044060 - DUBON NEIL CHRISTOPHER
Establishment Status	Active
Successor	NONE

January 27, 2026 04:12 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=034684&professionCode=020

AFFORDABLE RX INC. X

GENERAL INFO | ENFORCEMENT ACTIONS

Registration No: 034684

No Enforcement Actions Found

January 27, 2026 04:12 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=034684&professionCode=020

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA6102278	06-30-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-05-2025

AFFORDABLE RX INC
D/B/A AFFORDABLE SCRIPT
177 ROCKAWAY AVE
VALLEY STREAM, NY 11580

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
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SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-05-2025

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D/B/A AFFORDABLE SCRIPT
177 ROCKAWAY AVE
VALLEY STREAM, NY 11580

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Form DEA-223 (9/2016)

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH N/A	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Shipment of clinical trial materials only directly to patient's homes.	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☑ Other: Shipment of clinical trial drug direct to a patient's home.

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Almac Clinical Services, LLC

Physical Address: 4204 Technology Drive, Room 265

City: Durham State: NC Zip: 27704

Mailing Address (if different from physical address): 25 Fretz Road

City: Souderton State: PA Zip: 18964

Telephone: 919-479-8850 Toll Free # (NAC 639.708, NRS 639.23286): 833-424-0136

Fax: N/A Contact Email: acslicensing@almacgroup.com

Website: https://www.almacgroup.com/clinical-services/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Sheila Bizune

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24833

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Sheila Bizune	NV Pharmacist Registration #: 24833
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Almac Group Incorporated

Corporation/Organization Name: Almac Clinical Services, LLC

Mailing Address: 25 Fretz Road

City: Souderton State: PA Zip: 18964

Telephone: 215-660-8500 Email: acslicensing@almacgroup.com

Contact Person Name: Frances Smith

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Assistant Treasurer (title) for Almac Clinical Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Gareth Mark Weir

Print Name of Authorized Person

GMWei

Original signature of Authorized Person (copies or stamps not accepted)

11/10/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Gareth Mark Weir hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Assistant Treasurer (title) for Almac Clinical Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 10th day of November, 2025

Notary Public

Commonwealth of Pennsylvania - Notary Seal
Patricia Clymer, Notary Public
Montgomery County
My commission expires April 21, 2027
Commission number 1429493
Member, Pennsylvania Association of Notaries

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gareth Mark Weir

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

M. Weir

Original signature of Authorized Person (copies or stamps not accepted)

11/10/2025

Date

Board Use Only	Date Received: 11/17/25	Amount: $500 CK 104485

ALMAC

Partnering to Advance Human Health

Almac Clinical Services
25 Fretz Road
Souderton
PA 18964
T +1 (215) 660 8500
F +1 (215) 660 8501
E acslicensing@almacgroup.com
almacgroup.com

Date: 10 November 2025

Re: State Board Actions

Please note that we have responded "yes" to one of the disciplinary questions on the application. Below, please find full details of state actions involving Almac Clinical Services, LLC (Almac), covering both our Souderton, PA location and our Durham, NC location.

All state board actions are administrative in nature and none of Almac's licenses have been revoked or suspended as a result. It is also important to note that only the Alaska disciplinary action was issued against Almac's pharmacy licenses. All other state discipline was taken against Almac's wholesale licenses; however, we are disclosing full details of all disciplinary history for Almac in the interest of transparency.

Pharmacy Discipline:

Almac PA and Almac NC were the subject of an investigation by the Alaska Board of Pharmacy due to timing of a Pharmacist in Charge (PIC) change notification. This was settled by Almac PA and Alaska in June of 2022 and Almac NC and Alaska in September 2022 with a minimum civil fine. Almac PA and Almac NC continue to hold unrestricted non-resident pharmacy licenses in the state of Alaska.

Wholesale Discipline:

Two separate states (Ohio and Kansas) initiated administrative actions against Almac PA to obtain the out of state wholesale license. These actions were due to application submission timing only and did not involve any incident or action that was deemed harmful to patients within those states. In March 2021 (Ohio) and February 2022 (Kansas), Almac and the Boards of those states resolved the matters by settlement, whereby the Boards issued Wholesale Distributor licenses. As part of the settlements Almac agreed to pay minimal administrative fines.

In August 2023, Almac PA was issued a citation by the State of California. This citation was issued by California during the California wholesale license renewal process, in which Almac appropriately disclosed action taken by the Board of Pharmacy in Kansas for an administrative fine. The citation by California only reiterated the Kansas stipulation and was not issued due to any additional matter within the State of California. In this regard, Almac's License in CA was not restricted in any way, no fine was levied nor was any proof of abatement required.

Should the Board have further questions relating to this matter, please contact us via email at acslicensing@almacgroup.com.

Frances Smith
Regulatory Compliance Manager
Almac Clinical Services, LLC

10-NOV-2025
Date

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING
Anchorage Office

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Toll free fax: 907.269.8156

CERTIFIED# 7015 0640 0006 6002 5248
RETURN RECEIPT REQUESTED

September 29, 2022

Troy Suessmuth
Almac Clinical Services, LLC
25 Fretz Road
Souderton, PA 18964

RE: Case No. 2022-000215

Mr. Suessmuth,

This letter shall serve as formal notice to you that the Alaska Board of Pharmacy, during its September 22, 2022 meeting, adopted the Imposition of Civil Fine, presented to the Board by members of the staff from the Division of Corporations, Business and Professional Licensing. A copy of the Imposition of Civil Fine and Order, as adopted, is enclosed.

If you wish to pay with a credit card, a payment form has been included for your convenience.

Please be advised that your company was under official investigation by the Alaska Board. You may be required to report this license action and to disclose it when applying for licensure in other states. Should you have any questions regarding this matter, please do not hesitate to contact me at the address and telephone number listed above.

Sincerely,
DocuSigned by:
Greg Francois
A35E5A8A7A5F4B4...
Greg Francois,
Chief Investigator

cc: Office of Administrative Hearings
Sara Chambers, Director CBPL
Glenn Saviers, CBPL Deputy Director
Laura Carrillo, PHA Executive Administrator
Michael Bowles, Investigator
Marilyn Zimmerman, Paralegal II
Litigation File: 2022-000215 (Original)

GF:emd

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2022-000215

I, TROY SUESSMUTH, as an agent for Almac Clinical Services, LLC admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of Out-of-State Pharmacy License No. 176111, and over this Imposition of Civil Fine.

1. On January 11, 2022, we appointed a new Pharmacist-in-Charge. On January 31, 2022, the Board received our Change of Facility Manager form with the new Pharmacist-in-Charge notification; 20 days after the Pharmacist-in-Charge change occurred. **This is a violation of 12 AAC 52.200(c).**

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.75 and 12 AAC 52.200(c). We are agreeing to this Imposition of a Civil Fine of two hundred dollars ($200) in cash, certified check, or money order payable to the "State of Alaska" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

DIRECTOR OF QUALITY — 21 JUL 2022
Name/Title, Respondent — Date

SUBSCRIBED AND SWORN TO before me this 21 day of July, 2022, at Souderton, PA, Alaska.

SEAL

Commonwealth of Pennsylvania - Notary Seal
NORMA IRIS MONSERRAT GONZALEZ - Notary Public
Montgomery County
My Commission Expires Nov 1, 2022
Commission Number 1341819

Notary Public in and for Alaska
Norma Iris Monserrat Gonzalez
Notary Printed Name
My commission expires: 11/1/2022

CLP
EP

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Almac Clinical Services LLC)
)
Respondent)
Case No. 2022-000215

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2022-000215, regarding license number 176111, for failure to timely notify the Board of a Pharmacist-In-Charge change, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 22nd day of September, 2022, at Anchorage, Alaska.

ALASKA BOARD OF PHARMACY

By: Justin Ruffridge
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8162
Fax: 907.269.8195

CERTIFIED # 7019 0140 0000 6700 1518
RETURN RECEIPT REQUESTED

August 18, 2022

Troy Suessmuth
Almac Clinical Services, LLC
25 Fretz Road
Souderton, PA 18964

Re: Case No. 2021-001208 Corrected Order

Dear Troy Suessmuth,

There was a correction made to the date the Imposition of Civil Fine Board Order was signed. The date adopted and signed was June 16, 2022 and not June 24, 2022. This letter shall serve as formal notice to you that the Alaska Board of Pharmacy, during its June 16, 2022 meeting, adopted the Imposition of Civil Fine, presented to the Board by members of the staff from the Division of Corporations, Business and Professional Licensing. A copy of the Imposition of Civil Fine and Order, as adopted, is enclosed. Our records indicate that you have paid your fine.

Please be advised that your company was under official investigation by the Alaska Board. You may be required to report this license action and to disclose it when applying for licensure in other states. Should you have any questions regarding this matter, please do not hesitate to contact me at the address and telephone number listed above.

Sincerely,

DocuSigned by:
Greg Francois
A25B5A8A3A5B4B4...
Greg Francois,
Chief Investigator

cc: Office of Administrative Hearings
Sara Chambers, Director CBPL
Glenn Hoskinson, CBPL Deputy Director
Lisa Sherrell, PHA Executive Administrator
Michael Bowles, Investigator
Marilyn Zimmerman, Paralegal II
Brian Suprise, Paralegal II
Litigation File: 2021-001208 (Original)

GF:emd

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2021-001208

I, TROY SUESSMUTH, as an agent for Almac Clinical Services, LLC, admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of my Out-Of-State Pharmacy License No. 177964, and over this Imposition of Civil Fine.

1. On September 27, 2021, we appointed a new Pharmacist-in-Charge. On November 15, 2021, the Board received our Change of Facility Manager form with the new Pharmacist-in-Charge notification; 50 days after the Pharmacist-in-Charge change occurred. **This is a violation of 12 AAC 52.200(c).**

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.75 and 12 AAC 52.200(c). We are agreeing to this Imposition of a Civil Fine of three hundred dollars ($300) in cash, certified check, or money order payable to the "State of Alaska" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

TS
TROY SUESSMUTH DIRECTOR OF OPS — 12 APR 2022
Name/Title, Respondent — Date

SUBSCRIBED AND SWORN TO before me this 12th day of April, 2022, at Souderton, PA, Alaska. TS 12 APR 2022

SEAL

Patricia A Ashton
Notary Public in and for Alaska PA — TS 12 APR 2022

CZP
EP

Commonwealth of Pennsylvania - Notary Seal
Patricia A. Ashton, Notary Public
Montgomery County
My commission expires March 31, 2023
Commission number 1079525
Member, Pennsylvania Association of Notaries

PATRICIA A ASHTON
Notary Printed Name
My commission expires: March 31, 2023

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:

Almac Clinical Services, LLC

Respondent

Case No. 2021-001208

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2021-001208, regarding license number 177964, for failure to timely notify the Board of a Pharmacist-in-Charge change, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 16th day of June, 2022, at Soldotna, Alaska.

ALASKA BOARD OF PHARMACY

By: _____
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

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Filed by
FEB 18 2022

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 21-057
ALMAC CLINICAL SERVICES, LLC	)	
Registration No. 5-110642	)	

STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by and between the Kansas Board of Pharmacy (the "Board") and Almac Clinical Services, LLC located in Souderton, Pennsylvania ("Respondent") as follows:

1. The Board is represented herein by its attorney, Brenda L. Head of Frieden & Forbes, LLP, 1414 SW Ashworth Place, Suite 201, Topeka, Kansas 66604. The Respondent is represented herein by its attorney, Emma McAllister, VP Corporate & Legal, Almac Group, Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD, Northern Ireland.

2. The Board is the Kansas agency vested with the authority to carry out and enforce the provisions of the Kansas Pharmacy Law, K.S.A. 65-1626 *et seq.*, ("Act") including conducting hearings and proceedings to revoke, suspend or otherwise discipline a Kansas registration to operate as a non-resident wholesale distributor.

3. Respondent has made application to be registered by the Board as a non-resident wholesale distributor and was issued the conditional registration number 5-110642.

4. The Board's Investigation Member has received certain information, investigated and determined that there are reasonable grounds to believe that Respondent has committed one or more actions in violation of the Act which would justify the revocation or imposition of other disciplinary action against its Kansas Registration under the provisions of K.S.A. 65-1627(f) and

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the assessment of an appropriate fine against Respondent under the provisions of K.S.A. 65-1658.

5. Respondent hereby waives any further proof in this or any other proceeding before or initiated by the Board with respect to this matter, and upon motion duly made, seconded, and passed, the Board finds that:

A. On August 29, 2019, respondent submitted a Non-Resident Facility application to the Board. On October 4, and 7, 2019, the Board lawfully requested a satisfactory inspection dated within the last three (3) years which was required for registration by the Board.

B. Respondent failed to provide the Board with the requested satisfactory inspection and withdrew their application on November 22, 2019.

C. On September 17, 2020, Respondent submitted a Non-Resident Facility application to the Board which included a July 13, 2020 satisfactory inspection report from the Commonwealth of Pennsylvania Department of Health.

D. K.S.A 65-1643(c) provides that it is unlawful for any entity to distribute at wholesale any drugs in Kansas without a registration issued by the Board.

E. On Respondent's Supplemental Application Form S-350 dated August 5, 2020, Respondent self-reported shipping drugs and/or devices into Kansas eighty-eight (88) times in the previous 12 months when Respondent did not have a registration to do so in violation of K.S.A. 65-1643(c).

6. Upon motion duly made, seconded and passed, the Board finds and concludes that the conduct and violations found in the preceding paragraphs constitute violates the Act and the Regulations of the Board and are therefore grounds for disciplinary action against the

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Respondent's Kansas Registration provided for herein, pursuant to K.S.A. 65-1643(c), 65-1655 and 65-1627(f)(6).

7. The Board finds, concludes, and orders that the following disposition is just and appropriate under the circumstances:

A. ADMINISTRATIVE FINE. Within ten (10) days of the Board entering the Consent Order provided for herein, Respondent shall pay to the Kansas Pharmacy Board an administrative fine in the total amount of Ten Thousand Dollars ($10,000.00) [$5,000.00 fine for unlawful shipping without a registration and $5,000.00 fine for failing to respond to the Board's lawful request].

B. PROBATION. Respondent's Kansas Registration shall be placed on probationary status for a period of 5 years from the effective date of the Stipulation and Consent Order contemplated hereby ("Probation Period"). During the Probationary Period, the Respondent shall:

i. Provide the Board with un-redacted copies of any disciplinary action taken by a federal or state regulatory agency within ten (10) days of receipt;

ii. Provide the Board with un-redacted copies of Respondent's Kansas shipping manifest prior to entry into this Stipulation and Consent Order and every six (6) months thereafter during the probationary period; and

iii. Respondent shall obtain a satisfactory NABP inspection within eighteen (18) months of entry of this Stipulation and Consent Order and provide the Board with proof of the same.

C. CONDITIONAL REGISTRATION. It is agreed that upon Respondent's execution of this Stipulation, Respondent will be issued a conditional registration as a Non-Resident Kansas Wholesale Distributor Registration ("Respondent's Registration"), subject to

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the Probation Period requirements provided for herein, which will expire on the date of the next meeting of the Board at which approval of this Stipulation and Consent Order is considered. If the Board approves and adopts this Stipulation and Consent Order anticipated hereby, Respondent's Registration shall become unconditional, subject to the Probation Period requirements provided for herein .

D. OTHER REQUIREMENTS. Respondent acknowledges and agrees that as a condition of this Stipulation and Consent Order it must, and the Board further orders the Respondent to:

i. Comply fully with this Stipulation and Consent Order; and

ii. Comply fully with the Kansas Pharmacy Act, the Board's rules and regulations and all state and federal laws relating to Kansas pharmacies.

8. Respondent agrees that all information in the possession of the Board's Investigation Member, its staff, its investigators and or its attorney regarding the investigation which lead to this disciplinary action and all information discovered during the pendency of the disciplinary action may be disclosed to and considered by the Board as part of the presentation and consideration of the proposal of settlement in the form of this Stipulation and Consent Order and the Final Order provided for herein, with or without the presence of the Respondent or its attorney. In the event that this Stipulation and Consent Order and the Final Order provided for herein are not accepted and approved by the Board, the Respondent further waives any objection to the Board members' consideration of this Stipulation and Consent Order or the information mentioned in the preceding sentence and further agrees to waive any claim of due process violation or the right to seek the disqualification of any Board member as a result of the Board member's consideration of said document and information.

9. The stipulations contained herein shall not become binding until this Stipulation and Consent Order is approved by the Board and the Consent Order provided for herein is entered by the Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either the Board of the Respondent. The Respondent acknowledges that the approval of the Board's Investigation Member or its attorney shall not constitute the approval of the Board or bind the Board to approve this Stipulation and Consent Order.

10. The Respondent agrees that this Stipulation and Consent Order is in conformance with Kansas and federal law and the Board has jurisdiction to enter into it and enter the Final Order provided for herein. The Respondent further agrees, for purposes of this matter, that the Kansas Pharmacy Act, K.S.A. 65-1626 *et seq.* is constitutional on its face and as applied in this case.

11. This Stipulation constitutes the entire agreement of the parties and may only be modified by a subsequent writing signed by them. The agreement shall be interpreted in accordance with the laws of the State of Kansas.

12. The Respondent acknowledges that it has the following rights:

A. To have formal notice of charges served upon it;

B. To file a response to the charges;

C. To have notice of and participate in a formal adjudicative hearing with the Board or its designee making specific findings of facts and conclusions of law based only upon evidence admitted at such hearing; and

D. To take advantage of all applicable provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501 *et seq.* and the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.*

The Respondent freely waives these rights and acknowledges that said waiver is made voluntarily and in consideration of the Board's limiting the disciplinary action taken against it to those provided for herein. The Respondent further waives the right to seek reconsideration or appeal or otherwise contest this Stipulation and Consent Order provided for herein.

13. The Respondent acknowledges that it enters into this Stipulation and Consent Order freely and voluntarily after consultation with counsel of its choosing. The Respondent further acknowledges that it has read this Stipulation and Consent Agency order in its entirety, that it understands its legal consequences and that it agrees that none of its terms are unconscionable, arbitrary, or capricious.

14. Time is of the essence to this Stipulation and Consent Order. Respondent acknowledges and agrees that any violation of this Stipulation and Consent Order shall constitute a willful violation of a lawful Board order and grounds for further disciplinary action against it. The pendency of any disciplinary action arising out of an alleged violation of this Stipulation and Consent Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Stipulation and Consent Order.

15. This Stipulation and Consent Order constitutes the entire and final agreement of the parties. In the event any provision of this Stipulation and Consent Order is deemed invalid or unenforceable by a court of competent jurisdiction, it shall be severed and the remaining provisions of this Stipulation and Consent Order shall be given full force and effect.

16. Upon approval and entry of this Final Order by the Board, this Stipulation and Consent Order shall be a public record in the custody of the Board.

17. This Stipulation and Consent Order shall become effective on the day it is approved, accepted, and made an order of the Board by way of signature of the Board's authorized representative.

18. The Respondent acknowledges that it has been advised by the Board that it would have the right within 15 days after service of the Final Order provided for herein to file a petition for reconsideration with the Board and the right within 30 days after service of the Final Order provided for herein to file a petition for judicial review in the District Court of Shawnee County, Kansas in accordance with the Kansas Judicial Review Act, K.S.A. 77-601 *et seq.* and to serve such a petition for judicial review on the Kansas Board of Pharmacy by serving Alexandra Blasi, JD, MBA, its Executive Secretary at 800 SW Jackson St., Suite 1414, Topeka, KS 66612. The Respondent hereby waives those rights.

ENTERED AND EFFECTIVE this 18 day of February, 2022.

KANSAS BOARD OF PHARMACY

By: President
DR. JONATHAN BRUNSWIG, President

AGREED AND APPROVED BY:

Almac Clinical Services, LLC
25 Fretz Road, 3rd Floor
Souderton, PA 18964

DocuSigned by:
By: Robert Dunlop
31F63CB2DD1548D...

15-Feb-2022

Robert Dunlop
President Almac Clinical Services

Date

2/18/22

Dr. Terica Gatewood
Investigation Member

Date

DocuSigned by:
C4695759886A4CA...

15-Feb-2022

Emma McAllister
VP Corporate & Legal
Almac Group
Almac House
20 Seagoe Industrial Estate
Craigavon, BT63 5QD, Northern Ireland
+44 28 3839 5740
emma.mcallister@almacgroup.com
Attorney for Respondent

Date

2-15-22

Brenda L. Head, #15667
FRIEDEN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604
(785) 354-1100
bhead@fflawllp.com
Attorney for Kansas Board of Pharmacy

Date

DocuSign Envelope ID: 0216ECAD-4664-44F1-BF9C-1B7DA9F3DAE6

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing STIPULATION AND CONSENT ORDER was served by depositing same in the United States mail, postage prepaid, this 21st day of February, 2022 addressed to:

Brenda L. Head
FRIEDEN & FORBES, LLP
1414 SW Ashworth Place, Suite 201
Topeka, KS 66604

Almac Clinical Services, LLC
25 Fretz Road, 3rd Floor
Souderton, PA 18964

Emma McAllister
VP Corporate & Legal
Almac Group
Almac House
20 Seagoe Industrial Estate
Craigavon, BT63 5QD, Northern Ireland

Representative of the
KANSAS BOARD OF PHARMACY

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STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF: **CASE No. A-2020-0543**

Almac Clinical Services, LLC **License No. 01-2234800**
c/o Troy Suessmuth
25 Fretz Road
Souderton, PA 18964

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Almac Clinical Services, LLC (Almac), for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs, including controlled substances, while operating without a Board-issued license. Together, the Board and Almac are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Pursuant to ORC Section 4729.52(G)(1)(c)(ii), if a complete application for renewal has not been submitted by the sixty-first day after the renewal date specified in rules adopted by the board, the license is considered void and cannot be renewed, but the license holder may reapply for licensure.

3. Almac Clinical Services, LLC, submitted an application for reinstatement of Wholesaler Distributor of Dangerous Drug License, No. 01-2234800, which lists Troy Sussmuth, as the Responsible Person. All documents required per the terms of the reinstatement application were submitted by December 24, 2020.

FACTS

1. The Board initiated an investigation of Almac, Wholesaler Distributor of Dangerous Drugs License No. 01-2234800, related to Almac's illegal sales of dangerous drugs, including controlled substances, without a Board-issued license.

2. On or about March 9, 2021, the Board sent a Notice of Opportunity for Hearing to Almac, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

3. On or about April 5, 2021, Almac requested a hearing which was subsequently scheduled for August 10, 2021 and continued to a future date to pursue settlement negotiations.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Almac neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 9, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Almac agrees to pay to the Board a monetary penalty in the amount of $5,000.00. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. Almac's Wholesale Distributor of Dangerous Drugs license will be reinstated subject to satisfactory completion of all application and inspection requirements and payment of the fine.

5. Almac agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Almac agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Almac of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Almac by the Board and will NOT discharge Almac from any obligation under the terms of this Agreement.

7. Almac agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Almac understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Almac will operate.

10. Almac explicitly withdraws its request for administrative hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

DocuSigned by:
Troy Suessmuth
1857A20EBDD5454...

Troy Suessmuth, on behalf of,
Almac, Respondent

17-Sep-2021
Date of Signature

DocuSigned by:
C46957509886A4CA...

Emma McAllister, Attorney for Respondent

17-Sep-2021
Date of Signature

Rich Miller, RPh, President,
State of Ohio Board of Pharmacy

9/17/2021
Date of Signature

Henry Appel, Ohio Assistant Attorney General

9/17/2021
Date of Signature

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 03, 2023

DATED MATERIAL ENCLOSED

ALMAC CLINICAL SERVICES LLC
ATTN: [redacted]
25 FRETZ RD
SOUDERTON, PA 18964

RE: CI 2022 99287
ALMAC CLINICAL SERVICES LLC
OSD 7707

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- August 17, 2023: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- September 02, 2023: Any contest of the Citation by request for a formal Appeal must be received by the Board.

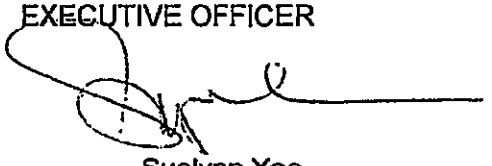
The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Suelynn Yee
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number	Name, License No
CI 2022 99287	ALMAC CLINICAL SERVICES LLC, OSD 7707

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
Bus. & Prof. Code § 4301 subd. (j)	Unprofessional Conduct - Violation of any statutes of this state or of the United States regulation controlled substances or dangerous drugs
Bus. & Prof. Code § 4301 subd. (n)	Unprofessional Conduct - Out of state disciplinary action
Bus. & Prof. Code § 4301 subd. (o)	Unprofessional conduct; assist in violation

CONDUCT:

Unprofessional Conduct – Business and Professions Code section 4301(j) authorizes the Board to take action against a licensee for the violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs. On February 18, 2022, the Kansas Board of Pharmacy placed Almac Clinical Services LLC on probation for five years and issued a $10,000 fine. According to the Stipulation and Consent Order, Almac Clinical Services LLC shipped drugs and/or devices into Kansas approximately 88 times prior to obtaining licensure.

Unprofessional Conduct – Business and Professions Code section 4301(n) authorizes the Board to take action against a licensee for the revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required. On February 18, 2022, the Kansas Board of Pharmacy placed Almac Clinical Services LLC on probation for five years and issued a $10,000 fine. According to the Stipulation and Consent Order, Almac Clinical Services LLC shipped drugs and/or devices into Kansas approximately 88 times prior to obtaining licensure.

Unprofessional Conduct – Business and Professions Code section 4301(o) authorizes the Board to take action against a licensee for violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency. On February 18, 2022, the Kansas Board of Pharmacy placed Almac Clinical Services LLC on probation for five years and issued a $10,000 fine. According to the Stipulation and Consent Order, Almac Clinical Services LLC shipped drugs and/or devices into Kansas approximately 88 times prior to obtaining licensure.

CITATION ISSUED ON: August 03, 2023

ALMAC

Partnering to Advance Human Health

Ownership Information

Almac Clinical Services LLC is 100% owned by Almac Group Incorporated.

Corporate Officers

Robert Dunlop- President

[redacted]

Graeme McBurney – Chief Operating Officer

[redacted]SQD

Emma McAllister-Secretary

[redacted]

Niall Patrick Harkin, Treasurer

[redacted]

Mark Weir, Assistant Treasurer

[redacted]

Current as of October 2024

ALMAC

Partnering to Advance Human Health

Almac Clinical Services
25 Fretz Road
Souderton
PA 18964
T +1 (215) 660 8500
F +1 (215) 660 8501
E acslicensing@almacgroup.com
almacgroup.com

Date: 17 October 2025

Re: Almac Clinical Services, LLC Explanation of Ownership

Almac Clinical Services (Almac) is a 100% privately held, full service global clinical supplies management company owned by Almac Group Inc., with US facilities in Durham, NC and Souderton, PA. As Almac is 100% owned by Almac Group Inc., there are no individual owners or stakeholders with a 10% or greater ownership interest in Almac Clinical Services. For additional details regarding our organizational structure, please refer to the attached organizational chart.

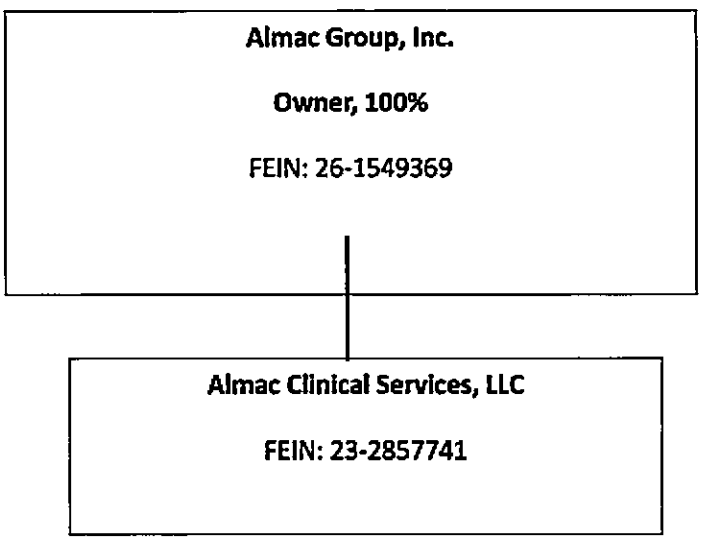
Attachment: Almac Organization Chart (1 page)

ALMAC

Partnering to Advance Human Health

Ownership Information

Almac Clinical Services LLC is 100% owned by Almac Group Incorporated.



Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALMAC CLINICAL SERVICES LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF OCTOBER, A.D. 2025.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 205071113

Date: 10-17-25

4467161 8300

SR# 20254296555

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Almac Clinical Services, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 4204 Technology Drive, Room 265

City Durham State NC Zip 27704

Mailing Address (if different from physical address) 25 Fretz Road

City Souderton State PA Zip 18964

Telephone 215-660-8500 Website https://www.almacgroup.com/clinical-services/

Licensing Company Email acslicensing@almacgroup.com

Section 2: Personal Information

First Sheila Middle Anita Last Bizune

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina- UNC Eshelman School of Pharmacy		08/02-05/06	
Address	**City**	**State**	**Zip**
301 Pharmacy Lane	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina		08/87-05/92	
Address	**City**	**State**	**Zip**
103 South Rd Ste CB9100	Chapel Hill	NC	27514
Diploma/Degree obtained, if any			
Bachelor of Arts (B.A.) Biology			

School Name		From - To (MM/YY – MM/YY)	
Rocky Mount High		08/85-06/87	
Address	**City**	**State**	**Zip**
1400 Bethlehem Rd	Rocky Mount	NC	27803
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
09/08-present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Almac Clinical Services			07/21-present	
Business Address	**City**		**State**	**Zip**
4204 Technology Drive	Durham		NC	27704
Phone	**Title**		**Number of Employed Hours**	
919-479-8850	Direct-to-Patient pharmacist-in-charge		+35,040 hours	

Description of Duties

Pharmacist dispensing of direct-to-patient shipments, prescription record keeping of all drug orders shipped from Almac to patient's homes. Oversee Pharmacy daily operations.

Business Name			From - To (MM/YY – MM/YY)	
Biologics by McKesson			12/13-10/19	
Business Address	**City**		**State**	**Zip**
11800 Weston Pkwy	Cary		NC	27513
Phone	**Title**		**Number of Employed Hours**	
800-856-1984	Pharmacy Manager of Fulfillment and Distribution		+60444	

Description of Duties

Oversee Pharmacy daily operations, dispensed patient prescriptions, record-keeping, staff management, inventory management, regulatory compliance.

Business Name			From - To (MM/YY – MM/YY)	
CVS Pharmacy			05/06-12/13	
Business Address	**City**		**State**	**Zip**
109 E Dabney Dr	Henderson		NC	27536
Phone	**Title**		**Number of Employed Hours**	
800-746-7287	Staff Pharmacist		+61320	

Description of Duties

Dispensed patient prescriptions, record-keeping, staff management, inventory management, regulatory compliance.

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sheila Bizune

Print Name (First, Last)

Sheila B

Original Signature (electronic, copies or stamps not accepted)

30 Oct 2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Durham

I, Sheila Bizune, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sheila B

Original Signature

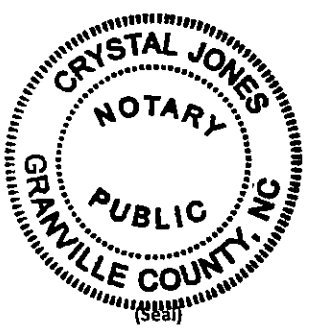
30 Oct 2025

Date

Subscribed and Sworn to before me this 30 day of October 2025.

Crystal Jones

Notary Public Signature



Inspection Details

Name	Almac Clinical Services, LLC	**Case #**		**Permit**	10511
		Person	Sheila Anita	**Inspection Date**	09/04/2025
Address	Room 265 4204 Technology Drive Durham, NC 27704	**Providing Info**	Bizune	**Inspection User**	Junez, Ruben
		Person In Charge	Sheila Anita Bizune	**Inspection District**	DISTRICT3
		Rx Volume/Date	The facility is currently not dispensing any medic		
# RPhs	9 pharmacists				
# Techs	0 Technicians N/A				
Follow-Up CAP	No	**Hours**	7:30 AM-3:30 PM M-F		
CAP Requested	No				
CAP Documentation Received	No	**Office**	No		
		Commercial Use	No		
Additional Documents	Yes	**Ship to Other States**	Yes		
		States Shipped To	Alaska, Arizona, Arkansas, California, Colorado, Florida, Georgia, Indiana, Kansas, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Rhode Island, South Carolina, West Virginia, Wisconsin		
Office Use	No				
Office Use Comments					
		Commercial Use Documented Clinical Indication	No		

Non-Sterile Compounding

Non-Sterile No

Does the pharmacy engage in Occasional Basic Non-Sterile Compounding?

Does facility engage in moderate or complex Non-Sterile compounding?

Does facility engage in Hazardous Drug Compounding?

Is there documented clinical indication for the approved medication?

Sterile Compounding

Sterile Compounding No

Does facility compound Immediate Use CSP?

Does facility compound Category 1 Sterile Compounding?

Does facility compound Category 2 Sterile Compounding?

Does facility compound Category 3 Sterile Compounding?

Does facility compound hazardous medications?

Does facility compound Allergenic Extracts?

Pharmacy Staffing

How many pharmacists are employed at the pharmacy: 9 pharmacists

How many technicians are employed at the pharmacy: 0 Technicians N/A

What is the P:T ratio at the time of inspection: N/A

How often is there only one pharmacist on duty:

If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift: N/A

How many technicians are usually on shift at a time: N/A

Are pharmacists asked to do any duties outside of the pharmacy :

What is the approved Pharmacist: Technician ratio? N/A

Pharmacy Volume

What is the average daily prescription volume of the pharmacy:
The facility is currently not dispensing any medic

Does pharmacy administer vaccines: No

What is the daily average of vaccines:

What staff members are administering vaccines and what type of vaccines:

How far behind is the pharmacy on filling and verifying prescriptions:
N

How long has this backlog persisted:

Does pharmacy conduct any point of care testing such as COVID:
No

What is the daily average of testing:

What staff is responsible for administering test and what is testing procedure:

Are administered vaccines reported to the appropriate vaccine registry:

Please explain:

Comments

The permitted facility performs packaging and labeling for clinical trials. The facility will distribute medication to clinics under IND for clinical trials. Drugs include, but are not limited to various frozen vials, tablets, creams, etc. Packing does not involve opening the drug. Containers are labeled according to client specifications for a particular clinical trial. The facility has quality control and safety assurance measures in place to ensure drugs are appropriately labeled and can be identified if needed. Drug storage and temperature controls are strictly monitored to avoid excursions.
In addition to the North Carolina Board of Pharmacy, this facility undergoes inspection by the US Food & Drug Administration, Department of Agriculture Food and Drug Protection, and the Medicines and Healthcare Products Regulatory Agency (European compliance).
No additional notes

General Pharmacy Regulations

	Answer	Question
1)	Not Applicable	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.
2)	Not Applicable	NCGS 90-85.15A (b) – Current registration of a pharmacy tech shall be readily available for inspection
3)	Not Applicable	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.
4)	Satisfactory	NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
5)	Satisfactory	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
6)	Satisfactory	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
7)	Not Applicable	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
8)	Not Applicable	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
9)	Satisfactory	NCGS 90-85.47 - Quality Assurance Program
10)	Not Applicable	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
11)	Not Applicable	NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.
12)	Not Applicable	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
13)	Not Applicable	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
14)	Satisfactory	NCGS 90-640 (b) - ID badge
15)	Not Applicable	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
16)	Not Applicable	21 NCAC GS 106-134.1 (b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)
17)	Not Applicable	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned

General Pharmacy Regulations

	Answer	Question
		by rphmgr. as represented in the application.
18)	Not Applicable	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
19)	Satisfactory	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
20)	Not Applicable	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
21)	Not Applicable	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
22)	Satisfactory	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
23)	Satisfactory	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
24)	Satisfactory	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
25)	Satisfactory	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
26)	Satisfactory	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.
27)	Not Applicable	21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.
28)	Satisfactory	21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.
29)	Not Applicable	21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
30)	Not Applicable	21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances
31)	Not Applicable	21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
32)	Not Applicable	21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
33)	Not Applicable	21CFR 1305.05 (a) - power of attorney on file at registered location.
34)	Not Applicable	21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
35)	Not Applicable	21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
36)	Not Applicable	21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
37)	Not Applicable	21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)
38)	Not Applicable	21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed
39)	Not Applicable	21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the prac- titioner.
40)	Not Applicable	21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.

General Pharmacy Regulations

	Answer	Question
41)	Not Applicable	21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
42)	Not Applicable	21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
43)	Not Applicable	21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
44)	Not Applicable	21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.
45)	Not Applicable	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
46)	Not Applicable	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPSapproved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
47)	Not Applicable	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.
48)	Not Applicable	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

NORTH CAROLINA BOARD OF PHARMACY

Facility: Almac Clinical Services, LLC
Address: Room 265 4204 Technology Drive Durham, NC 27704
Permit Type: Pharmacy
Permit #: 10511
Re-Issue Date: 11/10/2025
Expiration Date: 12/31/2026
Pharmacy Manager: Sheila Anita Bizune (#18281)

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

Permit #: 10511

NORTH CAROLINA BOARD OF PHARMACY

2026 Pharmacy

This is to certify that

Almac Clinical Services, LLC

doing business as

Almac Clinical Services, LLC

Room 265 4204 Technology Drive Durham, NC 27704 Durham

Has been renewed for the year ending December 31st 2026, as required by law and is issued to the pharmacist-manager pursuant to the representations made in application therefore. The issuance of this renewal permit is not complete and the permit is not valid until countersigned in the space indicated below by the pharmacist-manager as represented in the application. THIS PERMIT CERTIFICATE MUST BE CONSPICUOUSLY DISPLAYED IN THE PHARMACY TO WHICH IT APPLIES. Pharmacy permits are not transferable and may be revoked for the causes specified in the Law and the Rules and Regulations of the Board.

Sheila Anita Bizune (#18281)

11/10/2025
Re-Issued

PRESIDENT

EXECUTIVE DIRECTOR

NC Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517

North Carolina Board of Pharmacy

Only the top 250 records are shown

This serves as Primary Source Verification of the credential issued by the North Carolina Board of Pharmacy

Name:	Almac Clinical Services, LLC	**Permit #:**	10511
Address:	Room 265 4204 Technology Drive	**Permit Status:**	Active
City:	Durham	**Issue Date:**	03/22/2010
State/Zip:	NC 27704	**Expire Date:**	12/31/2026
Manager:	Sheila Anita Bizune	**Discipline:**	No

Information loaded from this database is current as of 11/10/2025 3:04:42 PM

ALMAC

Partnering to Advance Human Health

Almac Clinical Services
25 Fretz Road
Souderton
PA 18964
T +1 (215) 660 8500
F +1 (215) 660 8501
E acslicensing@almacgroup.com
almacgroup.com

Date: November 13, 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: Application for Non-Resident Pharmacy License

To Whom it May Concern,

Please find enclosed an application for a new permit as a Nevada Non-Resident Pharmacy, including all required supporting documentation and payment for the application fee.

Almac Clinical Services, LLC is a contract packager and shipper solely focused on clinical trial products. All pharmaceutical products handled by Almac Clinical Services, LLC fall under INDAs regulated by the Food and Drug Administration (FDA). Almac is seeking a new Nonresident Pharmacy License from the Nevada Board of Pharmacy.

Enclosed please find:

- A check made payable to Board of Pharmacy in the amount of $500.
- Completed and signed application.
- Attachment 1 – List of Officers and Ownership Information
- Attachment 2 – Explanation of Almac ownership
- Attachment 3 – Certificate of Good Standing
- Attachment 4 – Designated Representative Form
- Attachment 5 – A copy of the pharmacy's most recent inspection from the NC BOP
- Attachment 6 – A copy of the pharmacy's home state license
- Attachment 7 – License verification by the North Carolina Board of Pharmacy.
- Attachment 8 – Explanation of disciplinary history

Please feel free to contact me with any questions regarding the application at acslicensing@almacgroup.com.

Sincerely,

Taylor Lally
Regulatory Compliance Analyst
Almac Clinical Services, LLC

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: BRIGHTSIDE SPECIALTY PHARMACY

Physical Address: 431 N TUSTIN AVE STE C

City: SANTA ANA State: CA Zip: 92705

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 714-707-5115 Toll Free # (NAC 639.708, NRS 639.23286): 888-551-0857

Fax: 714-551-6822 Contact Email: tydusgroup@gmail.com

Website: www.brightsidespecialtyrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): TAN PHAM

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24907

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: TAN PHAM	NV Pharmacist Registration #: 24907
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: TAN PHAM	Credentials: PHARMACIST	%: 100
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CALIFORNIA

Parent Company (if any): _____

Corporation/Organization Name: TYDUS GROUP

Mailing Address: 431 N TUSTIN AVE STE C

City: SANTA ANA State: CA Zip: 92705

Telephone: 714-707-5115 Email: TYDUSGROUP@GMAIL.COM

Contact Person Name: TAN PHAM

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the OWNER (title) for BRIGHTSIDE SPECIALTY PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

TAN PHAM

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/31/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, TAN PHAM hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER (title) for BRIGHTSIDE SPECIALTY PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 2nd day of January, 2026

Notary Public

RRS2 NICO JORDAN BOYADJIAN COMM. # 2510395 NOTARY PUBLIC-CALIFORNIA ORANGE COUNTY MY COMM. EXP. JAN 21, 2029 RRS2

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TAN PHAM

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

12-31-2025

Date

Board Use Only	Date Received: 1/12/26	Amount: $500 cc

LIST OF OFFICERS AND DIRECTORS

Pursuant to NRS 639.231(2)(b) and NAC 639.214(5)(a), the following individuals serve as the Officers and Directors for the applicant entity.

Name — Title

Tan Phuc Pham — Chief Executive Officer (CEO)

Tan Phuc Pham — Chief Financial Officer (CFO)

Tan Phuc Pham — Secretary

Tan Phuc Pham — President

Tan Phuc Pham — Director

Tan Phuc Pham — Treasurer

I hereby certify that the information provided above is true and complete to the best of my knowledge.



Signature of Officer/Director

Tan Phuc Pham

Chief Executive Officer

Date: 12-31-2025

LIST OF TOP FOUR STOCKHOLDERS

Pursuant to NRS 639.231(3), the following individual(s) are the top stockholders of the applicant entity.

Tan Phuc Pham — 10,000 shares — 100% Ownership

I hereby certify that the information provided above is true and complete to the best of my knowledge.



Signature of Stockholder

Tan Phuc Pham

Sole Stockholder

Date: 12-31-2025

LIST OF STOCKHOLDERS HOLDING 10% OR MORE OF SHARES

Pursuant to NAC 639.214(4)(b), the following individual(s) hold ten percent (10%) or more of the ownership interest in the applicant entity.

Tan Phuc Pham — 100% Ownership

I hereby certify that the information provided above is true and complete to the best of my knowledge.



Signature of Stockholder

Tan Phuc Pham

Sole Stockholder

Date: 12-31-2025

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	TYDUS GROUP
Entity No.:	4218681
Registration Date:	12/17/2018
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of October 30, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 383972336

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler BRIGHTSIDE SPECIALTY PHARMACY
Pharmacy/Wholesaler License # (if applicable) _____
Physical Address 431 N TUSTIN AVE STE C
City SANTA ANA State CA Zip 92705
Mailing Address (if different from physical address) _____
City _____ State _____ Zip _____
Telephone 714-707-5115 Website WWW.BRIGHTSIDESPECIALTYRX.COM
Licensing Company Email TYDUSGROUP@GMAIL.COM

Section 2: Personal Information

First TAN Middle _____ Last PHAM
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X
Mailing Address [redacted]
City [redacted] State [redacted] Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
SAVANNA HIGH SCHOOL		08/99 - 05/03	
Address	**City**	**State**	**Zip**
301 N GILBERT ST	ANAHEIM	CA	92801
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
CALIFORNIA STATE UNIVERSITY FULLERTON		08/03 - 05/06	
Address	**City**	**State**	**Zip**
800 N STATE COLLEGE BLVD	FULLERTON	CA	92831
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
WESTERN UNIVERSITY OF HEALTH SCIENCE		08/06 - 05/10	
Address	**City**	**State**	**Zip**
309 E 2ND ST	POMONA	CA	91766
Diploma/Degree obtained, if any			
PHARM D.			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23 - PRESENT	[redacted]			
03/16 - 10/23				
10/14 - 02/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: BRIGHTSIDE SPECIALTY PHARMACY			From - To (MM/YY – MM/YY): 10/19 - PRESENT
Business Address: 431 N TUSTIN AVE STE C	City: SANTA ANA	State: CA	Zip: 92705
Phone: 714-707-5115	Title: PHARMACIST		Number of Employed Hours: 10,400
Description of Duties: VERIFY PRESCRIPTIONS, FILL RX, CONSULTATIONS			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, TAN PHAM, **certify that as the designated representative for**

BRIGHTSIDE SPECIALTY PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TPP I am at least 21 years of age;
3. TPP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TPP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TPP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TPP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TPP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

TAN PHAM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-31-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TAN PHAM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-31-2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of ORANGE

I, Tan Pham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-2-2026

Date

Subscribed and Sworn to before me this 2nd day of January 2026.

Notary Public Signature

NICO JORDAN BOYADJIAN
COMM. # 2510395
NOTARY PUBLIC-CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. JAN 21, 2029

(Seal)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy	X	Hospital Pharmacy	Clinic	Outsourcing Facility	Wholesaler	Hypodermic

Date: 11/4/2024 Inspector: Gigi Te

Firm: BRIGHTSIDE SPECIALTY PHARMACY Phone: (714) 707-5115

Address: 431 N TUSTIN AVE STE 431-C City: SANTA ANA Zip: 92705

Ownership: CORPORATION

Permit #: PHY57437 Permit Exp: 10/1/2025 DEA#: [redacted] DEA Exp: 11/30/2025

Date of Self Assessment Form: 8/19/2024 Other Permit #: N/A Date of DEA Inventory: 5/18/2023

Hours M-F: 9AM - 5:30PM Hours Saturday: CLOSED Hours Sunday: CLOSED

PIC **TAN P PHAM** RPH64459 Administrator

RPH Consultant

Staff	RPH Name:	License #:	Staff Name:	License #:
			ANDREA J GOMEZ VIRGEN	[redacted]
			DOUG MATSUSHITA	DRIVER
			JACQUELYN TRUONG	CLERK
			KASEY NGUYEN	CLERK

Inspector Remarks:

Here today for a full routine inspection, assisted by PIC Pham.

Brightside Specialty Pharmacy is an open-door independent retail pharmacy located in a shopping plaza. Primarily serving local walk-ins and general patient population. Pharmacy dispenses approximately 60-80 prescriptions daily, 25% new and 75% refills. Typically staffed with 1 RPh and 1 clerk.

PIC Pham stated PHY business consisted of 40% workers compensation, 20% Medi-Cal, 30% Medicare, 10% private and cash.
PHY no longer offers compounding as of 2020 per PIC Pham due to labor intensive and low reimbursement rate.
PHY offers immunization and recently got approved for California Vaccines for Children (VFC) – vaccine products get shipped to PHY by the state to provide vaccines at no cost to eligible children from birth to 18 years of age.
PHY has drug take-back receptable located inside pharmacy. DEA and State Registered. Reviewed receptable records and discussed practices for using receptable.

Delivery offered with their own driver three times a week.

Subscriber alert via brightsidespecialtyrx@gmail.com

The following items were reviewed during inspection:

- Consultation – no consultation observed due to low foot traffic.
- Original Permit/renewal license, Point to Language, Notice to Consumers – posted and visible to the public view.
- Biennial CS inventory – last completed on 05/18/23.
- Quarterly CII Reconciliation – last completed on 10/10/24.

- Self-Assessment – last completed on 08/19/24.
- CMEA Certificate in date.
- CURES reporting and PDMP enrollment – DigitalRx submits CURES daily and sends a copy to PHY. Last verified report 11/04/24.
- CII orders via CSOS – last verified orders 10/18/24.
- CII, CIII-V/RX invoices and hard copies separated and maintained for 3 years.
- DEA 106 last reported on 03/28/23 due to packaging discrepancy.
- Name Badge and job title.
- Ratio and Pharmacy staffing
- Security / Keys / Personal bags – pharmacy equipped with cameras and alarm.
- Sink with hot/cold running water.
- Stock/Refrigerator temperature log recorded daily.
- Reviewed Immunizations certificate and BLS – all current. CAIR reporting.
- Auto-Refill Program – PIC Pham stated PHY made notes of automatic refill on DigitalRx. PHY does not keep consent forms for those who are enrolled in automatic refill.. See corrections.
- No off-site storage waiver – all records are on site.
- Patient Center Labeling (Federal Caution, sans serf 12-point font) - checked 6 random labels and matched label to drug description, contents, amount and "Generic for". There was no English-language with the translated language on labels. See corrections.
- Caution on Label required for Drug Containing an Opioid
- RPh Initials RX label – educated PIC Pham to start initials Rx labels upon verification.
- RPh Initials on Phone Order – reviewed hard copies and PIC's initials are on phone orders.
- Deliver Service offered with their own driver three times a week. Written notice of consultation did not include day and time available for consultation. See corrections.
- Computer Software: DigitalRx
- Acquisition/Wholesalers: Cardinal, Auburn, SmartSource, IPCRx, IPC, Parmed, KeySource, Anda, PBA Health.
- Disposition/ Reverse distributor – last completed on 10/15/24 via RxReverse.
- Wholesalers/Manufacture Invoices maintained for 3 yrs – all on site.
- Drugs signed and received by RPH – PIC Pham stated he double checked every controlled substance invoice before TCH updating the system. Advised PIC Pham to co-sign or co-initial on invoices.
- Outdates are pulled monthly and quarantined away from active lots.
- Subscriber Alert
- Review hard copies - RX signed and dated by prescriber.

The following Policy and Procedures were reviewed:

- Quality Assurance Documentation – last med error reported 08/05/24.
- Impaired Employee / Theft / Diversion
- Temporary Absence of Pharmacist
- Interpretive Services
- Tech Job Description

Discussion

- Provided Board Inspection Brochure.
- CCR 1793.7 – RPHs to initial on prescription labels before dispensing to patients.
- CCR 1717.5 – Automatic-refill program.
- CCR 1776.3 - Collection Receptables in Pharmacies.
- BPC 4076.6 – Requirements for Translated Directions for Use.
- BPC 4059.5(g) - A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist.

DSCSA Investigation

- Reviewed pharmacy's current inventory and did not locate any HIV medication on the shelves. There were no bottles of any HIV

medications for me to visually or manually inspected.

- PIC Pham stated the last dispensing of HIV was in early 2020 for one patient when PHY license was first issued. Reviewed patient profile JP – first fill of Atripla on 04/25/20 (rx # 600916) followed by 4 refills, and last fill on 09/17/20 (rx# 601641). Product was purchased via McKesson. Asked PIC to login McKesson to pull up T3 report, PIC stated he does not have access anymore since 2021 when he switched to Cardinal. Then I asked PIC Pham to log in Cardinal and show me how to pull up track and trace documents. PIC Pham was able to show me the DSCSA T3 report.
- PIC Pham stated he stopped carrying HIV meds in 2020 because it was too expensive to order. Plus, PHY location does not have this type of business.
- Discussed checking for authorized trading partners (ATP) via https://www.gilead.com/medicines/authorized-distributors
- Discussed pharmacy's responsibilities regarding DSCSA and checking ATP. Under the DSCSA, every sale or transfer of a prescription drug must be accompanied with a record showing the chain of all sales or transfer of that drug, going back to the manufacturer. In the industry, this is known as drug's pedigree or T3 documentation – transaction information, transaction history, and transaction statement.

Topics to Educate

1. **BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test**.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.
   - Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.
   - Retain records for 3 years.

2. **BPC 4113 – PIC authority to make staffing decisions.**
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:
     - Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
     - Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
     - Vermin infestation that poses a risk to the safety or efficacy of medicine.

3. **BPC 4113.6** – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:
   - RPH on duty waives the requirement in writing during specified hours based on workload need.
   - The pharmacy is open beyond normal business hours (*i.e.*, before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
   - The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

   When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

4. **BPC 4113.1 – Reporting medication errors within 14 days from discovery.**

- Applies to "community pharmacies" – *i.e.*, any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
- Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.

5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.

6. BPC 4202 and 4231 – CE required for pharmacy technicians and pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

In order to complete this inspection, please submit all requested items to Inspector Te at Gigi.Te@dca.ca.gov within 14 days, no later than **Monday 11/18/24.**

1. A copy of revised Written Notice to Consultation to meet 6th day requirement.
2. A copy of three patients' prescription labels with the English-language included with the translated language.
3. A copy of signed automatic-refill program consent form.
4. Proof of RPH to co-sign or co-initial on controlled-substance invoices.
5. Proof of RPH initial on prescription labels before dispensing to patients.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) TAN PHAM

Inspector (sign) _____

Inspector (print) GIGI TE 11/07/2024

Owner(sign) _____

Owner(print) TAN PHAM

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 11/4/2024 Permit #: PHY57437

Time of Day: 11:37 AM

Name as shown on permit: **BRIGHTSIDE SPECIALTY PHARMACY**

Address: 431 N TUSTIN AVE STE 431-C City: SANTA ANA

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **CCR 1707.2(b)(1)(**	Duty to Consult. When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that: a pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week. In that, PHY's current written notice of consultation did not include days available for consultation.
2. **CCR 1717.5**	Automatic Refill Programs. In that, PHY had policy and procedure for automatic refill program but did not have records of consent forms
3. **BPC 4076.6(a)**	Patient-Centered Prescription Labels; Translated Directions for Use; Requirements. Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document. In that, PHY did not include the English-language version of the directions for use with the translated language.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

BPC 4059.5(g) Who May Order Dangerous Drugs or Devices: Exceptions; Compliance with Laws of All Involved Jurisdictions. Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

In that, PIC Pham double checked controlled substance invoices before inventory got updated in the system but did not cosign or co-initial next to TCH's initial.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____ Signed _____

Inspector (print) GIGI TE Print Name TRAN PHAM

Date 11/04/2024 Title PIC, owner

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

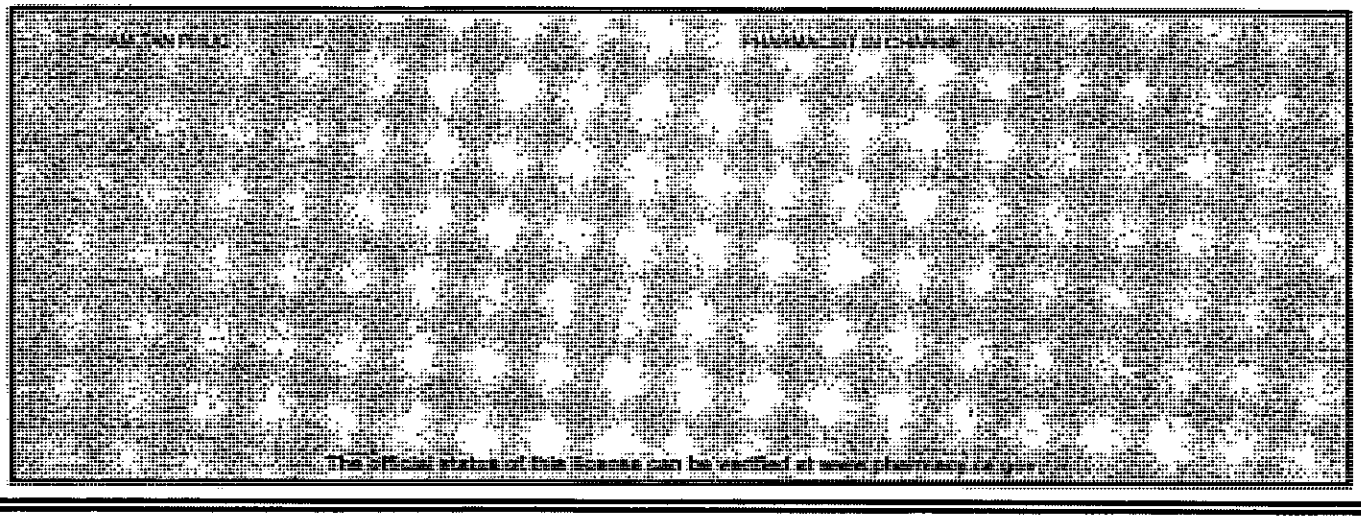
Retail Pharmacy Permit

LICENSE NO. PHY 61317

ISSUE DATE 9/29/2025

BRIGHTSIDE SPECIALTY PHARMACY
431 N TUSTIN AVE #C
SANTA ANA, CA 92705

The above is licensed with the State Board of Pharmacy as a Corporation



PLACE RENEWAL LICENSE HERE

VALID UNTIL 9/1/2026

RECEIPT NUMBER 00795430

This original license must be kept for the life of the license and posted in public view.

In accordance with the provisions of Chapter 9 of Division 2 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy when there is change of ownership, location, corporate officer, director, or shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 61317

NAME: BRIGHTSIDE SPECIALTY PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

431 N TUSTIN AVE #C
SANTA ANA CA 92705
ORANGE COUNTY

ISSUANCE DATE

SEPTEMBER 29, 2025

EXPIRATION DATE

SEPTEMBER 1, 2026

CURRENT DATE / TIME

JANUARY 15, 2026
9:4:44 AM

LICENSE RELATIONSHIPS

NAME: PHAM, TAN PHUC

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 64459 **PRIMARY STATUS:** CLEAR

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT8810384	11-30-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY-COLLECTOR	10-12-2025

TYDUS GROUP
DBA BRIGHTSIDE SPECIALTY PHARMACY
431 N TUSTIN AVE STE C
SANTA ANA, CA 927053821

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT8810384	11-30-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY-COLLECTOR	10-12-2025

TYDUS GROUP
DBA BRIGHTSIDE SPECIALTY PHARMACY
431 N TUSTIN AVE STE C
SANTA ANA, CA 927053821

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site BRIGHTSIDE SPECIALTY PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 431 N TUSTIN AVE STE C

City SANTA ANA State CA Zip 92705

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-707-5115 Website WWW.BRIGHTSIDESPECIALTYRX.COM

Licensing Company Email TYDUSGROUP@GMAIL.COM

Section 2: Personal Information

First TAN Middle _____ Last PHAM

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
SAVANNA HIGH SCHOOL		08/99 - 05/03	
Address	**City**	**State**	**Zip**
301 N GILBERT ST	ANAHEIM	CA	92801
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
CALIFORNIA STATE UNIVERSITY FULLERTON		08/03 - 05/06	
Address	**City**	**State**	**Zip**
800 N STATE COLLEGE BLVD	FULLERTON	CA	92831
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
WESTERN UNIVERISTY OF HEALTH SCIENCES		08/06 - 05/10	
Address	**City**	**State**	**Zip**
309 E 2ND ST	POMONA	CA	91766
Diploma/Degree obtained, if any			
PHARM. D			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23 - PRESENT	[redacted]			
03/16 - 10/23				
10/14 - 02/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
BRIGHTSIDE SPECIALTY PHARMACY			10/19 - PRESENT
Business Address	**City**	**State**	**Zip**
431 N TUSTIN AVE STE C	SANTA ANA	CA	92705
Phone	**Title**		
714-707-5115	PHARMACIST		
Description of Duties			
VERIFY PRESCRIPTIONS, FILLED RX, CONSULT, MANAGE STAFF			

Business Name			From - To (MM/YY – MM/YY)
WALGREENS			11/10- 09/19
Business Address	**City**	**State**	**Zip**
5695 ALTON PKWY	IRVINE	CA	92618
Phone	**Title**		
949-726-0716	PHARMACIST		
Description of Duties			
VERIFY PRESCRIPTIONS, FILLED RX, CONSULT, MANAGE STAFF			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TAN PHAM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-31-2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of ORANGE

I, Tan Pham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-2-2026

Date

Subscribed and Sworn to before me this 2nd day of January 2026.

Notary Public Signature

NICO JORDAN BOYADJIAN
COMM. # 2510395
NOTARY PUBLIC-CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. JAN 21, 2029

(Seal)

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH R10068	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FC3459988 ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: CDE, LLC DBA CITY DRUG

Physical Address: 131 10TH ST

City: EVANSTON State: WY Zip: 82930

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: 307-789-4000 Toll Free # (NAC 639.708, NRS 639.23286): 1-877-789-4001

Fax: 307-444-4000 Contact Email: CANNONRPH@GMAIL.COM

Website: WWW.CITYDRUGEVANSTON.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew Cannon

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: ANDREW CANNON	NV Pharmacist Registration #: 24942
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: ANDREW CANNON

Business Name: CDE, LLC DBA CITY DRUG

Business Address: 131 10TH ST

City: EVANSTON State: WY Zip: 82930

Telephone: 801-633-7974 Email: CANNONRPH@GMAIL.COM

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the MANAGING MEMBER (title) for CDE, LLC DBA CITY DRUG (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

ANDREW CANNON

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/9/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, ANDREW CANNON hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the MANAGING MEMBER (title) for CDE, LCC DBA CITY DRUG (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

VERONICA SOMMERVILLE
NOTARY PUBLIC
STATE OF WYOMING
COMMISSION ID: 169272
MY COMMISSION EXPIRES: 11/28/2029

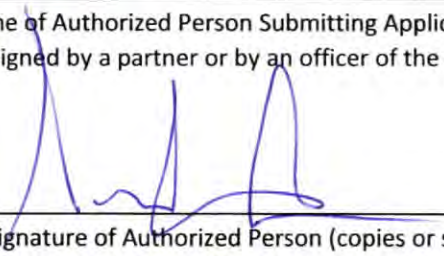
SUBSCRIBED AND SWORN TO
Before me, a notary public this 9th day of January 20 25

Veronica Sommerville
Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANDREW CANNON

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

1/9/26

Date

Board Use Only	Date Received: 1/14/26	Amount: $500-CK 1070

STATE OF WYOMING
Office of the Secretary of State

I, CHUCK GRAY, Secretary of State of the State of Wyoming, do hereby certify that according to the records of this office,

CDE,LLC

is a

Limited Liability Company

formed or qualified under the laws of Wyoming did on **December 27, 2013**, comply with all applicable requirements of this office. Its period of duration is Perpetual. This entity has been assigned entity identification number **2013-000656243.**

This entity is in existence and in good standing in this office and has filed all annual reports and paid all annual license taxes to date, or is not yet required to file such annual reports; and has not filed Articles of Dissolution.

I have affixed hereto the Great Seal of the State of Wyoming and duly generated, executed, authenticated, issued, delivered and communicated this official certificate at Cheyenne, Wyoming on this 8th day of January, 2026 at 11:40 AM. This certificate is assigned ID Number 094965130.

Chuck Gray

Secretary of State

Notice: A certificate issued electronically from the Wyoming Secretary of State's web site is immediately valid and effective. The validity of a certificate may be established by viewing the Certificate Confirmation screen of the Secretary of State's website https://wyobiz.wyo.gov and following the instructions displayed under Validate Certificate.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CDE, LLC DBA CITY DRUG

Pharmacy/Wholesaler License # (if applicable) R10068

Physical Address 131 10TH ST

City EVANSTON State WY Zip 82930

Mailing Address (if different from physical address) SAME

City _____ State _____ Zip _____

Telephone 307-789-4000 Website WWW.CITYDRUGEVANSTON.COM

Licensing Company Email CANNONRPH@GMAIL.COM

Section 2: Personal Information

First ANDREW Middle WHITELEATHER Last CANNON

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
ROSEMAN UNIVERSITY OF HEALTH SCIENCES			08/09-05/12
Address	**City**	**State**	**Zip**
10920 S RIVER FRONT PKWY	SOUTH JORDAN	UT	84905
Diploma/Degree obtained, if any			
PHARM D			

School Name			From - To (MM/YY – MM/YY)
BRIGHAM YOUNG UNIVERSITY			08/05-07/09
Address	**City**	**State**	**Zip**
212 HINCKLEY CENTER	PROVO	UT	84602
Diploma/Degree obtained, if any			
UNDERGRAD - NO DEGREE			

School Name			From - To (MM/YY – MM/YY)
WEST JORDAN HIGH SCHOOL			08/02-06/05
Address	**City**	**State**	**Zip**
8136 S 2700 WEST	WEST JORDAN	UT	84008
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21-PRESENT	[redacted]			
04/13-04/21				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
CDE, LLC DBA CITY DRUG			07/12 - CURRENT	
Business Address		**City**	**State**	**Zip**
131 10TH ST		EVANSTON	WY	82930
Phone	**Title**		**Number of Employed Hours**	
307-789-4000	PHARMACIST/MANAGING MEMBER		6480	
Description of Duties				
OVERSEE DAILY PHARMACY OPERATIONS INCLUDING STANDARD PHARMACIST DUTIES AS WELL AS ENSURING PROPER DOCUMENTATION AND RECORD KEEPING OF PRESCRIPTIONS, INVENTORY AND AUDITS.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANDREW CANNON

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/9/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Wyoming, ss. County of Uinta

I, Veronica Sommerville, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-9-2026

Date

Subscribed and Sworn to before me this 9 day of Jan, 2026.

Veronica Sommerville

Notary Public Signature

VERONICA SOMMERVILLE
NOTARY PUBLIC
STATE OF WYOMING
COMMISSION ID: 169272
MY COMMISSION EXPIRES: 11/28/2029

(Seal)

National Association of Boards of Pharmacy®
Universal Inspection Form

Inspector Name:	Clayton Barker		**Type(s) of practice Type "X" for all that apply**
Type and Purpose of Inspection	**Retail/Routine**	**Traditional retail**	YES
Inspection Performed by (NABP, State, etc):	**Wyoming Board of Pharmacy**	**Open to the Public**	YES
E-Mail Address	cannonrph@gmail.com	**Closed Door**	NO
Legal Business Name:	CDE, LLC	**Drive-through window**	NO
Address:	131 10th Street	**Mail/Deliver (in state)**	YES
City:	Evanston	**Mail/Deliver (out-of-state list below)**	YES
State:	WY	**Veterinary Pharmacy**	YES
Zip Code:	82930	**Institutional**	NO
Telephone number:	307-789-4000	**Long-Term Care**	NO
Fax number:	307-444-4000	**Telepharmacy**	NO
Start Time: 24-hour format (13:00)	1400	**Central Fill/Processing/Shared Services**	NO
End Time: 24-hour format (13:00)	1700	**Specialty Pharmacy**	NO
		Nonsterile Compounding	YES

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.
General Pharmacy- None
Nonsterile - None

Pharmacy Hours of Operation	**Check if 24/7**	
	Open	**Closed (X)**

	Start Time: (24-hour format)	End Time: (24-hour format)	
Sunday			X
Monday	0900	1800	
Tuesday	0900	1800	
Wednesday	0900	1800	
Thursday	0900	1800	
Friday	0900	1800	
Saturday	0900	1300	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Ian Borovatz	[redacted]	613682
Non-Sterile Compounding Superviser	Ian Borovatz		613682
Sterile Compounding Supervisor	N/A	N/A	N/A
Hazardous Compounding Supervisor	Ian Borovatz		613682

Personnel Employed Pharmacists/Technicians/Technicians in Trng/Interns etc..	Name	Title	License or registration available and current (Y/N)
1	Ian Borovatz	RPh/PIC	4370
2	Andrew W Cannon	RPh/Owner	
3	Zachary Thomas Fitch	RPh	4118
4	Shelbi Faddis	RPT	T3114
5	Adam Wade Cannon	RPT	T2513
6	Samantha Knudsen	RPT	T2871
7	Stephen Cannon	RPT	T2135
8	Sheri Anderson	TNT	TT3977
9	Jordan Bowie	TNT	TT3750
10	Dustin Hart	TNT	TT3959

Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Wyoming Board of Pharmacy	City Drug Evanston, LLC	Resident Retail Pharmacy	R10068 06/30/2026
Wyoming Board of Pharmacy	City Drug Evanston, LLC	Controlled Substance Registration	525CD11 06/30/2026
DEA	City Drug	Federal	FC4359988

Inspector Notes: List states in which Non-Resident licenses are held: ***Arizona, Colorado, Florida, Idaho, Minnesota, Montana, North Dakota, Oregon, South Dakota, Utah***

Attachments: NONE

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	X	Telepharmacy	N/A
Open to the Public	X	Central Fill/Processing/Shared Services	N/A
Closed Door	N/A	Specialty Pharmacy	N/A
Drive-through window	N/A	Handles Medical Marijuana	N/A
Mail/Deliver (in state)	X	Nuclear Pharmacy	N/A
Mail/Deliver (out-of-state list below)	X	Manufacturer	N/A
Veterinary Pharmacy	X	Wholesale Distributor	N/A
Investigational Drugs, Clinical Trials/Research	N/A	Provide prescription drugs for "Office Use"	N/A
Institutional	N/A	Outsourcing Facility	N/A
Long-Term Care	N/A	Nonsterile Compounding	X
HMO/PBM only	N/A	Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)	N/A	Sterile Compounding	N/A
Internet Pharmacy (Refill Rx)	N/A	Sterile Hazardous Drug Compounding	N/A

Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply			
CNSPs with controlled substance(s)	YES	Specific types:	
CNSPs with vitamins or nutritional supplements	YES	Solid oral preparations	YES

CNSPs for INDs	NO	Liquid oral preparations	YES
CNSPs which are essential copies of a commercially available drug product on the Drug Shortage List or justified by a documented medical need for an individual patient - If so, list:	NO	Otic preparations	YES
CNSPs sold OTC	NO	Rectal preparations	YES
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed	NO	Vaginal preparations	YES
Patient specific:		Topical preparations:	
CNSPs for animals	YES	Creams	YES
CNSPs for human patients	YES	Gels	YES
Distributed (eg non patient-specific):		Ointments	YES
CNSPs for animals	NO	Lotions	YES
CNSPs for human patients	NO	Nasal and sinus preparations:	
CNSPs to practitioners for office use	NO	Nasal sprays	YES
CNSPs to hospitals, clinics, or surgery centers	NO	Nasal irrigations	YES
Types of CNSPs:		Other (please list):	NONE
Aqueous	NO		
Non-Aqueous	NO		
Specific Types	NO		

	Facility Size In Square Feet and Number of PECs		**Personnel**
Total Pharmacy size:	**3000 ft**	Total Pharmacists:	**4**

Nonsterile Compounding Room size:	400 ft	Number of Compounding Pharmacists	3
Nonsterile Compounding powder hoods number:	1	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	115	Total Student Interns:	0
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	2	Total Technicians:	14
Sterile Compounding Ante Room size:	N/A	Number of Compounding Technicians	4
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are certified?	5
Sterile Compounding Number LAFW hoods/areas:	N/A	Of technicians, how many are techs-in-training?	9
Sterile Compounding Number BSC hoods:	N/A	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	N/A	Total Other Unlicensed Personnel:	2
Negative Pressure Sterile HD Room size:	N/A	Ratio #Tech:#RPh present at time of inspection:	This does not apply to Wyoming
Sterile HD Compounding Number of BSC hoods:	N/A	Total Pharmacist Hours Per Week:	80
Sterile HD Compounding Number of CACI hoods:	N/A	Total Technician Hours Per Week:	500
Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample) ***N/A***		Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason. ***N/A***	

	Volume Dispensed		**Volume Distributed**
Total Prescriptions Dispensed/day:	***APPROX 375***	Total Orders Distributed/day:	***N/A***
% Veterinary Prescriptions	***1.0%***	% Veterinary Orders	***N/A***
% Controlled Substance Prescriptions	***16%***	% Controlled Substance Orders	***N/A***

% Nonsterile Compounded Prescriptions	19.0%	% Nonsterile Compounded Orders	N/A
% Sterile Compounded Prescriptions	0.0%	% Sterile Compounded Orders	N/A
% Hazardous Drugs (HD) Prescriptions	16.0%	% Hazardous Drugs (HD) Orders	N/A

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Wyoming	8248	N/A	N/A
Arizona	27	N/A	N/A
Utah	471	N/A	N/A
Idaho	48	N/A	N/A
Oregon	3	N/A	N/A
Montana	19	N/A	N/A
Colorado	9	N/A	N/A
Minnesota	200	N/A	N/A
North Dakota	368	N/A	N/A
South Dakota	15	N/A	N/A
Florida	10	N/A	N/A
Wisconsin	4	N/A	N/A

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: City Drug LLC
e-Profile ID: 818927
Inspection Date: 9/9/2025

		Finding	Notes
Section 1	**General Pharmacy**		
1-1	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	Ian
1-2	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 plus
1-3	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
1-4	What Software does the pharmacy use?		Pioneer
1-5	Are photographs allowed during the inspection (no PHI)?	Yes	
1-6	List of additional personnel **interviewed as part of the inspection, including name and title:**		
1-7	Verify the pharmacy maintains a professional reference library in text or electronic format:	Yes	
1-8	Does the pharmacy's internet firewall allow for electronic access?	Yes	
1-9	Current WY pharmacy laws?	Yes	
1-10	Current edition of Facts & Comparisons (or comparable reference)	Yes	
1-11	Current drug interaction text.	Yes	
1-12	Wyoming BOP quarterly newsletters by access to the Board website?	Yes	
1-13	FDA Orange Book?	Yes	
Section 2	**Unit Dose or Unit of Use packaging**		
2-1	Does the pharmacy dispense unit dose or unit of use packaging? If "No" mark 2-2 thru 2-6 as "N/A"	Yes	
2-2	**Unit Dose or Unit of Use packaging is labeled with the following?**		
2-3	Brand and/or generic name of the drug	Yes	
2-4	Strength	Yes	
2-5	Manufacturer's expiration date (if repackaged by the pharmacy, is the expiration date the lesser of the manufacturer's expiration date or 12 months?	Yes	
2-6	Are unit dose or unit of use dispensed at patient or facility request?		Patient specific inside facility
Section 3	**Long-Term care facilities**		

3-1	Does the Pharmacy provide services to any long-term care facilities? If "No" mark 3-2 thru 3-14 "N/A"	No	
3-2	Does the pharmacy provide an ancillary drug box to the LTCF?	N/A	
3-3	Are there written policies and procedures on file at the pharmacy?	N/A	
3-4	Is the policy reviewed and approved annually by the consultant pharmacist of the facility and the facility's director of nursing?	N/A	
3-5	Is the ancillary drug supply stocked and re-stocked by a pharmacist, technician, tech-in-training, or intern?	N/A	
3-6	Does the pharmacy recieve an order or verify that a prescription exists before removal of controlled substance from the ancillary drug supply?	N/A	
3-7	Does the pharmacy provide first dose pharmacy services?	N/A	
3-8	Are services for the limited purpose of ensureing drugs/devices are attainable to meet the needs of residents or if the provider pharmacy cannot provide the services on an ongoing basis?	N/A	
3-9	Did the provider pharmacy obtain approval from the LTCF to obtain first dose services for its residents?	N/A	
3-10	Does the provider pharmacy provide a valid verbal, electronic, or paper medication order to the first dose pharmacy?	N/A	
3-11	Is the pharmacy a provider pharmacy?	N/A	
3-12	Is there a written agreement/contract available beween the pharmacy and LTCF?	N/A	
3-13	Is there a drug recall policy that is readily retrievable? (Must include a procedure for immediate discontinuation of any recalled drug/device and subsequent notification of the	N/A	
3-14	Are there arrangements for providing 24/7 services, either directly or by contract with another pharmacy?	N/A	
Section 4	**Types of Practice Additional Questions**		
4-1	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states*	Yes	Approximately 20 percent total
4-2	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
4-3	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
4-4	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales*	N/A	
4-5	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales*	N/A	

4-6	Does the pharmacy have a remote pick up site? If "Yes" list site	No	
Section 5	**General Operations and Licensure**		
5-1	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
5-2	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	15 April, 2024
5-3	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	
5-4	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
5-5	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	Was currently thinking of utilizing a VPP inspection, however, with this inspection, it will suffice b/c it is NABP recognized.
5-6	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
5-7	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
5-8	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
5-9	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
5-10	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued end date, end response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
5-11	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
5-12	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
5-13	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record if they have a certificate, and what tests they perform (CLIA) waiver information, expiration date.*	Yes	Strep, UTI
5-14	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	2 Years for State Standards, 10 years total for all
5-15	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	10 Years
5-16	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Mostly Electronic, Prior records are hard copies (older)

5-17	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically,
5-18	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Utilizing Pioneer, no way to delete records, when a record is closed out, it is still stored in system.
5-19	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable? If "Yes" list site.	N/A	No records stored off site, all records on site are secured and stored in a locked room.
Section 6	**Personnel**		
6-1	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Owner and PIC reviews periodically and always checks BOP website for good standing. Utilized Pester Comp Software for tracking.
6-2	Are all pharmacy technicians and technicians-in-training wearing name badges with appropriate designation and identifying themselves in all telephone conversations while on duty?	Yes	
6-3	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Pester Comp Software
6-4	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	Yes	CPR, Immunization
6-5	Are combat methamphatamine act policies in place?	Yes	
Section 7	**Facility and Security** **If any part of a question is no, enter "No" and explain the observation.**		
7-1	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Peak Alarm system, notifies Owner, PIC which then notifies 911.
7-2	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	
7-3	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Everything is connected to a Battery back-up system. A hard lock down would be initiated and Pharmacist would ensure everything is locked down.
7-4	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
7-5	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
7-6	Is there a sink with hot and cold running water?	Yes	
7-7	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	Yes	All documented and disposed of properly
7-8	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	In-Mar
7-9	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	In-Mar
7-10	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	Pharmacist works at front counter, they can provide a private area for counseling.

7-11	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	69 degrees
7-12	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Currently using website that is logged daily, logs are maintained and temperature is set for min/max, an alarm will alert if temperature falls out of the setting.
7-13	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
7-14	Are the refrigerator and freezer restricted to drug products only and have sufficient capacity to serve the needs of the pharmacy (no food)?	Yes	
7-15	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Temperature is monitored and logged.
7-16	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	35 degrees
7-17	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Same as refridgerator
7-18	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	Yes	-10
7-19	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Battery backup system attatched to both
7-20	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Battery backup system attatched to both
7-21	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
7-22	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	Eye Con, Pixel
7-23	Is there documentation of quarterly calibration and verification of accuracy?	Yes	Logged Quarterly
7-24	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	
Section 8	**Product Receipt and Inventory**		
8-1	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	Cardinal Health, API, TOP RX, Anda System is built into Pioneer that researches each of these when Drugs are ordered
8-2	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
8-3	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	Yes	Created a checklist to track and monitor any source to verify compliance on an annual basis. Anytime a new vendor is used the checklist will be utilized.
8-4	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	No	
8-5	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	Comp software

8-6	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
8-7	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	DSCSA Information
8-8	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	
8-9	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	
8-10	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	Yes	Notice warning on Ozympic, researched Ozympic origination once an alert was researched.
8-11	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	
8-12	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
8-13	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	No	
8-14	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	Yes	Owner and PIC using CSOS
8-15	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	
8-16	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
8-17	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
8-18	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
8-19	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory upudated daily in computer, compared with paper perpetual.
8-20	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Local Police, BOP, DEA
8-21	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
8-22	Is the Schedule II perpetual inventory log reconciled no less than quarterly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	

8-23	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	**Monthly**
8-24	Is the CS inventory taken during the first week of May available for review?	Yes	
8-25	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	Yes	Electronic
8-26	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	No	
8-27	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	
8-28	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
8-29	How often is active-stock examined for drugs past the expiration date?		Monthly
8-30	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	7-10 days without a pick-up returned to shelf
8-31	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	
Section 9	**Prescription Processing**		
9-1	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Technician, Pharmacist, Updated and checked anytime new prescription with patient.
9-2	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Pioneer is set up to identify as pet.
9-3	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
9-4	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Mostly the process to call the presciber and verify, all providers are well known and identified by Pharmacist.
9-5	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Compares addresses of patient, then provider to ensure.
9-6	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
9-7	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
9-8	Are hard copies of prescription maintained in a separate file?	Yes	
9-9	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	All information identified by Authorizing Pharmacist
9-10	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR alert is during initial fill process, and cannot bypass.

9-11	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications.	Yes	
9-12	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	No	
9-13	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
9-14	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Pioneer program is fed into PDMP and research is conducted.
9-15	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	PER PDMP regulations with Wyoming
9-16	Are errors immediately corrected once they are notified? (end of next business day)	Yes	
9-17	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	There is no override capability, Pioneer is programmed by Pharmacy owner and PIC.
9-18	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Pioneer
9-19	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	
9-20	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	Yes	Pioneer has feature to identify as pet and what type.
9-21	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Always by Pharmacist.
9-22	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Technician and Pharmacist initials on Label
9-23	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Pioneer, has a user function set up by Owner
9-24	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
9-25	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
9-26	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
9-27	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
9-28	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	

9-29	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
9-30	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	N/A	
9-31	Do the emergency kits contain any compounded products? *If so, indicate whether sterile*	N/A	
9-32	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	N/A	
9-33	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
9-34	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
Section 10	**Patient Counseling and Communication**		
10-1	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	
10-2	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Sales Technician assigned, a pharmacist is usually present also at the front desk, and verifies.
10-3	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	
10-4	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Sales Technician assigned
10-5	Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	
10-6	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	Yes	
10-7	Is patient counseling provided for <u>delivered</u> prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Calls during fill process
10-8	Is patient counseling provided for <u>mailed</u> prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Calls during fill process
10-9	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	Both by scanning and inserts.
10-10	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	Both by scanning and inserts.
10-11	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	Yes	iPledge, Isotrentinoin, Tikosyn
10-12	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Placed in pioneer under remarks.
10-13	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	An on call pharmacist is assigned daily for pharmacist access
10-14	Are processes in place to handle a drug recall?	Yes	
10-15	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	

10-16	Does the take-back program include controlled substances?	N/A	
10-17	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
Section 11	**Quality Assurance/Quality Improvement Program(Informational)**		
11-1	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Just incooperated and building program Mpestel, Pharmacy owner oversees and holds
11-2	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronic
11-3	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a	Yes	All will be listed in SOP and available electronically
11-4	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	Since this is new with the pharmacy there are no records but Owner will meet monthly.
11-5	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronic
11-6	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
11-7	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
11-8	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
11-9	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
11-10	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Analysis will be conducted by PIC, and Owner. Monthly meetings will be held.
11-11	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
11-12	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	Yes	
11-13	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Planned Monthly according to PIC
11-14	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

11-15	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
11-16	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Med-watch, Wyoming BOP, FDA
11-17	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
11-18	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
11-19	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	New program
11-20	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
11-21	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	
Section 12	**Non-Sterile compounding**		
1.00	Does the pharmacy perform non-sterile compounding? If the Pharmacy performs non-sterile compounding utilize Nonsterile 795 checklist. This includes "Magic Mouthwash"	Yes	***See USP 795 Checklist provided to PIC for reference (did not inspect)***
Section 13	**Immunization services**		
13-1	Does the pharmacy provide immunization services? If answer "No" 13-2 thru 13-7 is "N/A"	Yes	
13-2	Is there a pharmacist/technician at this location registered with the Board to prescribe and administer immunizations?	Yes	
13-3	Does the pharmacist have a current certification in basic life support?	Yes	
13-4	Is a copy of the immunization questionnaire and consent form completed for each person receiving an immunization and kept on file for a minimum of 2 years?	Yes	
13-5	Is a copy of the protocol posted in a private space or maintained in the emergency kit?	Yes	
13-6	Is the emergency kit maintained and readily retrievable to manage an acute allergic reaction?	Yes	
13-7	Does the immunization questionnaire and consent form address all required information? (1) - Documentation that the pharmacist has discussed the side effects with the patient. (2) - A recommendation that the patient stays in the vicinity for 15 minutes and how to seek treatment for side effects if the patient chooses not to stay.	Yes	

	Does the pharmacy enter a record of the immunization in the Wyoming immunization registry operated by the Department of Health? **Wyoming State Statute: 33-24-157 site: wyir.health.wyo.gov**	Yes	Electronic.

Discrepancies Noted	Corrected Y/N	Due Date to Correct
36.2 - Per USP 795 10.1 - Terminology: Each CNSP Label must state the date, or the hour and date, beyond which the preparation cannot be used and must be discarded (ie the "BUD") BUD's for CNSP's are calculated in terms of hours, days, or months. BUD's and expiration dates are not the same, An expiration date identifies the time during which a conventionally manufactured product, API, or add substance can be expected to meet the requirements of a compendial monograph, if one exists, or maintain expected quality, provided it is kept under the prescribed storage conditions. The Expiration date limits the time during which a conventionally manufactured product, API, or added substance may be dispensed or used. ***In order to comply with USP795 requirements, I recommend the Pharmacy contact the software company and add this into the system. (I have seen other pharmacies***		

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: City Drug, LLC

e-Profile ID: 818927

Inspection Date: 9/9/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)			
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? *If no, go to compliance statements.*	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***	Yes	Separate rooms for compounding, SOPs for maintaining equipment.	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***	Yes	Training program and set frequencies for review/evaluation	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***	Yes		3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***	Yes		6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***	Yes		4.2, 11

1.6	**Equipment:** The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***	Yes	All powders are manipulated within Hoods	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***	Yes	SOP's cover all spills, Hazordous, Non-Hazardous.	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***	Yes	All changes are documented and kept in pharmacy sortware.	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***	Yes		9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***	Yes		11, 12 USP <1163>

1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***	Yes	Full investigation protocol in event of error/recall	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***	Yes		11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***	Yes		11, 13.2
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***	Yes		12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to the compliance statements.***	Yes		1.1.4

2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes	SOP's reviewed annually, prior to Staff review.	1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes	Initial training program thru LP3 Network. Yearly competencies, tests performed and documented on site.	2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes	Followed per SOPs	2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14

3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes	All personnel involved in Compounding must be trained	2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes	Documented in Pestile	2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes	No current accomodations authorized. But per policy	3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1

6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes	separate areas.	3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes	Area is "only" designated for compounding.	4.1

8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes	Kept in pestle, initial tmperature reviewed and monitored.	4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes	NIST Certified annually	4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***	[redacted]	69 degrees F	4.2

12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes		4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** *List the agents in the Inspector Notes.*		70 percent Isopropyl, Alcohol, Bleach, Contec TB1-3300	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? *Review compounding cleaning logs.* *If no, go to compliance statements.*	Yes	Cleaning logs documented in Pestle	5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1

15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** *If yes, list the type(s) in the Inspector Notes.*	Yes	CVE	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** *Review certification reports, calibration records, and cleaning logs.* *If no, go to compliance statements.*	Yes		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** *If no, inspector should describe observations.*	Yes		6.1

18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent) ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes		6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes	Certified every 6 months	6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1

20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Food, Drug, and Cosmetic Act, Section 503A, requirement as well. If the API comes from a repackager, the pharmacy must be able to confirm the manufacturer of the API was registered as an Establishment with FDA.***	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		Either purified (reverse osmosis) or Sterile Water	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes	All components are inspected by trained staff prior to introduction for use in compounding.	6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations (797), 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes	None observed	6.2.2

23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5

26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** *If no, go to the compliance statements.*	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes	BUD Determined by testing data from supplier SOP, or 3d party testing sent by pharmacy	7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? *If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.*	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1

28.3	MFR includes the type of container-closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14

29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	No	All calculations are done on MFR	7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes.***	Yes	Pharmacists reviews all wieghts, methods performed, and final visual inspection of compounded product	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9

31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	No	BUD is listed as epiration date.	9
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: This is a USP recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CSNP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A.***	Yes		9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	No	Only option in software is expiration date.	10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3

36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	Yes		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	Yes		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	Yes		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label, and describe what specific steps of the monograph were not followed.***	Yes		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	Yes		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	Yes		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4

42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	N/A		10.4
42.1	**Non-preserved, Aqueous Dosage Forms:** The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	Yes		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5

44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	Yes		10.5
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	Yes		10.5

44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	Yes		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes	1 Complaint reviewed. No adverse events,	12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	Yes	Container Failure	12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2

47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documented the implementation of the recall.	N/A		12.1

49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A		3.1

54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Diclofenac 3 percent cyclobenzaprine, 3 percent tetracaine, 4 percent cream, Naltrexone 3 mg capsules	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes	Linked via pharmacy software	7, 7.1 Box 2

58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes	Must be entered into pharmacy software/CR in order to complete	7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes	Logged into software	14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes	weighed capsules	7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2

58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes	Naltrexone 18 mg capsules, testosterone 2,5 mg troches	8, 8.1, 9
59.1	CSNP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes	each step logged into software	8.1, 14
59.8	CSNP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal.	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12

61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

NS <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (e.g., long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	PIC (DP)	Pharmacist	Technician	Technician	Technician	Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes	Yes	Yes	Yes	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes	Yes	Yes	Yes	
1.12	The training record for spill management is complete.	Yes	Yes	Yes	Yes	Yes	

2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
2.4	The annual competency assessment for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
2.8	The annual competency assessment for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Yes	Yes	Yes	Yes	Yes	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Yes	Yes	Yes	Yes	Yes	
2.12	The annual competency assessment for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
3.0	**The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record.** *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	N/A	N/A	N/A	N/A	N/A	

WYOMING STATE BOARD OF PHARMACY

Hereby certifies that the business whose name appears on this certificate has complied with the provisions of Wyoming Statute 33-24-101 *et seq* and Wyoming Statute 35-7-1001 *et seq* (if applicable) and/or rules and regulations regarding registration through the expiration date of **June 30, 2026**.

Resident Retail Pharmacy

City Drug 131 10th Street Evanston, WY 82930

Registration Number: R10068
Original Issue Date: 05/25/2011
Date Issued: 05/19/2025
WY Controlled Substance Number: 525CD11
DEA Registration: FC4359988

Fee Paid: $150.00

Authorized Schedules: II, III, IV, V

Fee Paid: $40.00

City Drug
131 10th Street
Evanston, WY 82930

Tosha Williamson
Secretary-Treasurer
Wyoming State Board of Pharmacy

Permit must be displayed in a conspicuous location at the registrant's business address



State Board of Pharmacy

Back to Results

Details

Name	City Drug
City	Evanston
State	WY
Pharmacist in Charge:	Borovatz, Ian Mark

License Type	Business Controlled Substance Registration
License Number	525CD11
License Status	Active
License Issue Date	5/19/2025
License Expiration Date	6/30/2026
Original License Date	2/1/2014

License Type	Resident Retail Pharmacy Registration
License Number	R10068
License Status	Active
License Issue Date	5/19/2025
License Expiration Date	6/30/2026
Original License Date	5/25/2011

Disciplinary Action	None

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: CDE, LLC DBA City Drug
Address: 131 10th St
City: Evanston State: WY Zip: 82930
I hereby authorize the Wyoming Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.
Signature of Applicant

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
R10068	Active	5-11-2011	6-30-2026

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☒ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☒ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☒ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☒ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☐ Yes ☐ No

Signature of State Official	Title	State	Date	S.
Roxanne Johnson	Licensing Specialist	WY	1-12-2026	

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC4359988	08-31-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-09-2025

CDE, LLC DBA: CITY DRUG
CITY DRUG
131 10TH ST
EVANSTON, WY 829303421

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC4359988	08-31-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-09-2025

CDE, LLC DBA: CITY DRUG
CITY DRUG
131 10TH ST
EVANSTON, WY 829303421

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CDE, LLC DBA CITY DRUG

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) R10068

Physical Address 131 10TH ST

City EVANSTON State WY Zip 82930

Mailing Address (if different from physical address) SAME

City EVANSTON State WY Zip 82930

Telephone 307-789-4000 Website WWW.CITYDRUGEVANSTON.COM

Licensing Company Email

Section 2: Personal Information

First ANDREW Middle WHITELEATHER Last CANNON

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY OF HEALTH SCIENCES			08/09-05/12	
Address		City	State	Zip
10920 S RIVER FRONT PKWY		SOUTH JORDAN	UT	84095
Diploma/Degree obtained, if any				
PHARMD				

School Name			From - To (MM/YY – MM/YY)	
BRIGHAM YOUNG UNIVERSITY			08/05-07/09	
Address		City	State	Zip
212 HINCKLEY CENTER		PROVO	UT	84602
Diploma/Degree obtained, if any				
UNDERGRAD - NO DEGREE				

School Name			From - To (MM/YY – MM/YY)	
WEST JORDAN HIGH SCHOOL			08/02-06/05	
Address		City	State	Zip
8136 SOUTH 2700 WEST		WEST JORDAN	UT	84088
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
04/21-PRESENT				
From - To (MM/YY – MM/YY)				
04/13-04/21				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CDE, LLC			02/14-Present
Business Address	**City**	**State**	**Zip**
131 10th Street	Evanston	WY	82930
Phone	**Title**		
307-789-4000	Managing Member		
Description of Duties			
Pharmacist/Owner			

Business Name			From - To (MM/YY – MM/YY)
Elevation Family Pharmacy			01/2018-Present
Business Address	**City**	**State**	**Zip**
5080 Robert J Mathews Pkwy Suite 170	El Dorado Hills	CA	95762
Phone	**Title**		
(833) 626-1480	Limited Partner		
Description of Duties			
Limited Owner (5%)			

Business Name			From - To (MM/YY – MM/YY)
BVP, LLC			08/19-Present
Business Address	**City**	**State**	**Zip**
950 North HWY 414	Mountain View	WY	82939
Phone	**Title**		
307-224-410	Managing Member		
Description of Duties			
Pharmacist/Owner			

Business Name			From - To (MM/YY – MM/YY)
Vyv RX, LLC			06/25-Present
Business Address	**City**	**State**	**Zip**
1050 Medical Drive Suite 102	Brigham City	UT	84302
Phone	**Title**		
866-898-7498	Partner		
Description of Duties			
20% Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANDREW CANNON

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/9/26

Date

Please have this section completed in the presence of a Notary Public.

State of Wyoming, ss. County of Uinta

I, Veronica Sommerville, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/9/26

Date

Subscribed and Sworn to before me this 9 day of Jan, 26.

Veronica Sommerville

Notary Public Signature

VERONICA SOMMERVILLE
NOTARY PUBLIC
STATE OF WYOMING
COMMISSION ID: 169272
MY COMMISSION EXPIRES: 11/28/2029

(Seal)

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	**Application Type (check all applicable)**	**Pharmacy Type (check all applicable)**	**Services the Pharmacy will Provide (check all applicable)**
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH__ _____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☑ Retail/Community ☑ Dangerous drugs ☑ Controlled substances DEA #: FF4266070 ☑ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		**Ownership Type (check applicable box)**
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☐ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☑ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Formulate Rx Pharmacy

Physical Address: 1049 Willa Springs Dr. STE 1051

City: Winter Springs State: FL Zip: 32708

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 407-707-9797 Toll Free # (NAC 639.708, NRS 639.23286): 877-340-0042

Fax: 407 972 1010 Contact Email: licensure@formulateRx.com

Website: formulateRx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Steven Miller

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24929

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Steven Miller	NV Pharmacist Registration #: 24929
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Formulate Rx Pharmacy, LLC

Mailing Address: 1049 Willa Springs Dr. STE 1051

City: Winter Springs State: FL Zip: 32708

Telephone: 407 707 9797 Email: licensure@formulateRx.com

Contact Person Name: Steven Miller

Please check type of partnership (NAC 639.214) ☑ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☑ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist In Charge (title) for Formulate Rx Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Steven Miller

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/15/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Steven Miller hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for Formulate Rx Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28th day of Oct, 2025

Notary Public

Notary Public State of Florida
Bao Ngoc Nguyen
My Commission HH 453626
Expires 10/11/2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steven Miller

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/15/2025

Date

Board Use Only	Date Received: 12/21/24	Amount: $500 Ck 1171113656

Formulate Rx Pharmacy

1049 Willa Springs Dr, STE 1051
Winter Springs, FL 32708
877-340-0042
admin@formulaterx.com
www.formulaterx.com

Ownership Structure: Formulate Rx Pharmacy

This statement serves to confirm the ownership structure of **Formulate Rx Pharmacy, LLC**, a Limited Liability Company (LLC) operating under the DBA **Formulate Rx Pharmacy**.

Formulate Rx Pharmacy, LLC is wholly owned by **Encore Health Holdings, LLC**, which is the sole member of Formulate Rx Pharmacy, LLC.

Encore Health Holdings, LLC is a Limited Liability Company with ownership equally divided between the following individuals:

- **Steven Miller**: 50% ownership
- **Quoc-Thien Tran**: 50% ownership

This ownership structure reflects the current and accurate arrangement of Formulate Rx Pharmacy, LLC and its parent entity, Encore Health Holdings, LLC.

State of Florida
Department of State

I certify from the records of this office that FORMULATE RX PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on October 30, 2023.

The document number of this limited liability company is L23000494814.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on May 7, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Seventh day of January, 2026

Secretary of State

Tracking Number: 8312642349CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Formulate Rx Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH35085

Physical Address 1049 Willa Springs Dr STE 1051

City Winter Springs State FL Zip 32708

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 4077079797 Website www.formulaterx.com

Licensing Company Email licensure@formulaterx.com

Section 2: Personal Information

First Steven Middle R Last Miller

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Florida - College of Pharmacy		08/14 - 05/18	
Address	**City**	**State**	**Zip**
1225 Center Dr	Gainesville	FL	32610
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of South Florida		08/12 - 05/14	
Address	**City**	**State**	**Zip**
4202 E Fowler Ave	Tampa	FL	33620
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
State College of Florida		08/09 - 05/12	
Address	**City**	**State**	**Zip**
5840 26th St W	Bradenton	FL	34207
Diploma/Degree obtained, if any			
Associate of Arts			

School Name		From - To (MM/YY – MM/YY)	
Booker High School			
Address	**City**	**State**	**Zip**
3201 N Orange Ave	Sarasota	FL	34234
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/25 - Current	[redacted]			
10/24 - 12/25				
11/23 - 11/24				
10/22 - 10/23				
09/19 - 09/22				
09/18 - 09/19				
09/16 - 09/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Formulate Rx Pharmacy			01/24 to Present	
Business Address		**City**	**State**	**Zip**
1049 Willa Springs Dr STE 1051		Winter Springs	FL	32708
Phone	**Title**		**Number of Employed Hours**	
407 707 9797	Owner / Pharmacist in Charge		5200	
Description of Duties				
Oversee all pharmacy operations, including the preparation and dispensing of customized compounded medications tailored to individual patient needs, ensuring compliance with USP and state/federal regulations.				

Business Name			From - To (MM/YY – MM/YY)	
MiMed Pharmacy			12/2018 - 09/2022	
Business Address		**City**	**State**	**Zip**
7758 NW 46th St		Doral	FL	33166
Phone	**Title**		**Number of Employed Hours**	
305 733 0187	Owner / Pharmacist in Charge		7940	
Description of Duties				
Oversaw all pharmacy operations, including the preparation and dispensing of customized compounded medications tailored to individual patient needs, ensuring compliance with USP and state/federal regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Steven Miller, **certify that as the designated representative for** Formulate Rx Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SM I am at least 21 years of age;
3. SM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Steven Miller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/15/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steven Miller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/15/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Seminole

I, Steven Miller, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/15/2026

Date

Subscribed and Sworn to before me this 15 day of January, 2026.

Notary Public Signature

RYLEE PRICE
Notary Public - State of
Commission # HH 654000
My Comm. Expires Mar 20, 2029
Bonded through National Notary Assn.

(Seal)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 29813
Insp # 203139

NAME	PERMIT NUMBER	DATE OF INSPECTION
Formulate Rx Pharmacy, LLC	35085	12/22/2025
DOING BUSINESS AS FORMULATE RX PHARMACY		
STREET ADDRESS 1049 Willa Springs Drive STE 1051	**TELEPHONE #**	**EXT**
CITY WINTER SPRINGS	**COUNTY** SEMINOLE	**STATE/ZIP** FL/32708

Additional Information

Business Operation Hours

M-T-W-TH-F N	Monday Y
Tuesday Y	Wednesday Y
Thursday Y	Friday Y
Saturday N	Sunday N

Registered Pharmacist / Intern / Tech

License # PS58675	Licensee Name Steven Miller
License Type Registered Pharmacists	
License # PS 58711	Licensee Name QUOC THIEN TRAN
License Type Registered Pharmacists	
License # 51433	Licensee Name Gina Pitaluga
License Type Pharmacy Tech	
License # 92982	Licensee Name Jenely Cabezudo
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FF4266070	

License Relations

Pharmacy Affiliate

MILLER, STEVEN R	License # 58675
TRAN, QUOC-THIEN	License # 58711

RX DPT MGR/COR/POR

MILLER, STEVEN R	License # 58675

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	N/A
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

INV359 - Community Requirements

Insp # 203139 — Formulate Rx Pharmacy, LLC — File # 29813

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *Uses Trimvirate Env Services*	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.]	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	Yes
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] *Opening inventory 6/2024 newer facility*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	Yes
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

INV359 - Community Requirements

Insp # 203139

Formulate Rx Pharmacy, LLC

File # 29813

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Reviewed inspection with pharmacist Steven.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

BLAKE, ELLEN

Date:12/22/2025

Representative:

Steven Miller

Date:12/22/2025

Your license number is PH 35085.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
FEBRUARY 14, 2025	**PH 35085**	**153760**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2027**

FORMULATE RX PHARMACY, LLC
Formulate Rx Pharmacy
1049 WILLA SPRINGS DRIVE
STE 1051
WINTER SPRINGS, FL - 32708

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
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FORMULATE RX
PHARMACY, LLC
Formulate Rx Pharmacy

REGISTRANT SIGNATURE

Department of Health

Formulate Rx Pharmacy, LLC

Formulate Rx Pharmacy

License Number: PH35085

Data As Of 1/12/2026

Profession	Pharmacy
License	PH35085
License Status	Clear/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2027
License Original Issue Date	04/15/2024
Address of Record	1049 Willa Springs Drive STE 1051 WINTER SPRINGS, FL 32708
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
MILLER, STEVEN R	PHARMACY AFFILIATE	PHARMACIST	58675	02/19/2024
MILLER, STEVEN R	RX DPT MGR/COR/POR	PHARMACIST	58675	04/02/2024

Name	Relationship	Profession	License	Effective Date
TRAN, QUOC-THIEN	PHARMACY AFFILIATE	PHARMACIST	58711	02/19/2024

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FF4266070	09-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-11-2024

FORMULATE RX PHARMACY, LLC
DBA FORMULATE RX PHARMACY
1049 WILLA SPRINGS DR
STE 1051
WINTER SPRINGS, FL 32708

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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FORMULATE RX PHARMACY, LLC
DBA FORMULATE RX PHARMACY
1049 WILLA SPRINGS DR
STE 1051
WINTER SPRINGS, FL 32708

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Formulate Rx Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (If applicable) PH35085

Physical Address 1049 Willa Springs Dr. STE 1051

City Winter Springs State FL Zip 32708

Mailing Address (If different from physical address) _____

City _____ State _____ Zip _____

Telephone 407 707 9797 Website Formulate Rx. com

Licensing Company Email licensure @formulate Rx. com

Section 2: Personal Information

First Quoc - Thien Middle N/A Last Tran

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bishop Moore Catholic High School			2006 - 2010	
Address		**City**	**State**	**Zip**
3901 Edgewater Dr.		Orlando	FL	32804
Diploma/Degree obtained, if any				
High School				

School Name			From - To (MM/YY – MM/YY)	
Nova Southeastern University			2014 - 2018	
Address		**City**	**State**	**Zip**
3300 S. University Dr.		Fort Lauderdale	FL	33328
Diploma/Degree obtained, if any				
Doctor of Pharmacy, PharmD				

School Name			From - To (MM/YY – MM/YY)	
USF University of South Florida			2-010 - 2014	
Address		**City**	**State**	**Zip**
4202 E. Fowler Ave		Tampa	FL	33620
Diploma/Degree obtained, if any				
Bachelor of Sciences				

School Name			From - To (MM/YY – MM/YY)	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2025 - Current	[redacted]			
10/2024 - 11/2025				
11/2023 - 11/2024				
10/2022 - 10/2023				
09/2019 - 08/2022				
07/2018 - 08/2019				
08/2014 - 08/2018				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Formulate Rx Pharmacy	04/2024 - Current

Business Address	City	State	Zip
1049 Willa Springs Dr. #1051	Winter Springs	FL	32708

Phone	Title
407 707 9797	Pharmacist

Description of Duties
- Ensure medications are safe, appropriate, & accurately prepared & dispensed according to prescription & applicable laws. Counsel patients, oversee technicians, monitor drug-drug interation.

Business Name	From - To (MM/YY – MM/YY)
Optum	06/23 - 03/24

Business Address	City	State	Zip
5700 Dot Com Ct. STE 1050	Oviedo	FL	32765

Phone	Title
800 880 1188	Pharmacist

Description of Duties
Central fulfillment center. ensure medications are accurately ~~dispepreale~~ dispensed. Oversaw technicians.

Business Name	From - To (MM/YY – MM/YY)
Mined Pharmacy - CLOSED	04/21 - 09/22

Business Address	City	State	Zip
7758 NW 46th St.	Doral	FL	33166

Phone	Title
305 929 8473	Pharmacist

Description of Duties
Ensure medications are safe, appropriate, & accurately prepared & dispensed according to the prescription & applicable laws. Counsel patients, oversee technicians, monitor drug-drug interactions.

Business Name	From - To (MM/YY – MM/YY)
CVS	06/19 - 03/21

Business Address	City	State	Zip
3770 N. Goldenrod Rd	Winter Park	FL	32792

Phone	Title
407 670 0888	Pharmacist

Description of Duties
Transferred to South Florida 09/2019
Ensure medications are safe, appropriate, & accurately prepared & dispensed according to the prescription & applicable laws. Counsel patients, monitor drug-drug interaction, provide immunizations.

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Quoc-Thien Tran

Print Name (First, Last)

Quoc-

Original Signature (electronic, copies or stamps not accepted)

12/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Seminole

I, Quoc-Thien Tran, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Quoc-

Original Signature

1/14/26

Date

Subscribed and Sworn to before me this 14th day of January 2026.

Notary Public Signature

ISAAC PASTRANA
Notary Public - State of Florida
Commission # HH 696216
My Comm. Expires Jul 10, 2029
Bonded through National Notary Assn.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Formulate Rx Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH35085

Physical Address: 1049 Willa Springs Dr STE 1051

City: Winter Springs State: FL Zip: 32708

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 4077079797 Website: www.formulaterx.com

Licensing Company Email: licensure@formulaterx.com

Section 2: Personal Information

First: Steven Middle: R Last: Miller

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Florida - College of Pharmacy		08/14 - 05/18	
Address	**City**	**State**	**Zip**
1225 Center Dr	Gainesville	FL	32610
Diploma/Degree obtained, if any			
Doctor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
University of South Florida		08/12 - 05/14	
Address	**City**	**State**	**Zip**
4202 E Fowler Ave	Tampa	FL	33620
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		**From - To (MM/YY – MM/YY)**	
State College of Florida		08/09 - 05/12	
Address	**City**	**State**	**Zip**
5840 26th St W	Bradenton	FL	34207
Diploma/Degree obtained, if any			
Associate of Arts			
School Name		**From - To (MM/YY – MM/YY)**	
Booker High School		08/04 - 05/08	
Address	**City**	**State**	**Zip**
3201 N Orange Ave	Sarasota	FL	34234
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/25 - Current	[redacted]			
10/24 - 12/25				
11/23 - 11/24				
10/22 - 10/23				
09/19 - 09/22				
09/18 - 09/19				
09/16 - 09/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Formulate Rx Pharmacy			01/24 to Present
Business Address	**City**	**State**	**Zip**
1049 Willa Springs Dr STE 1051	Winter Springs	FL	32708
Phone	**Title**		
407 707 9797	Owner		

Description of Duties

Oversee all pharmacy operations, including the preparation and dispensing of customized compounded medications tailored to individual patient needs, ensuring compliance with USP and state/federal regulations.

Business Name			From - To (MM/YY – MM/YY)
Pharmetika			12/23 to Present
Business Address	**City**	**State**	**Zip**
8030 Excelsior Dr STE 303	Madison	WI	53717
Phone	**Title**		
800 222 4767	Account Executive / Sales		

Description of Duties

Manage the full sales cycle in a remote environment using CRM tools, build long-term client relationships through consistent follow-up and needs-based consultations.

Business Name			From - To (MM/YY – MM/YY)
MiMed Pharmacy			12/2018 - 09/2022
Business Address	**City**	**State**	**Zip**
7758 NW 46th St	Doral	FL	33166
Phone	**Title**		
305 733 0187	Owner		

Description of Duties

Oversaw all pharmacy operations, including the preparation and dispensing of customized compounded medications tailored to individual patient needs, ensuring compliance with USP and state/federal regulations.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steven Miller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/15/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Seminole

I, Steven Miller, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/15/2026

Date

Subscribed and Sworn to before me this 15 day of January, 2026

Notary Public Signature

RYLEE PRICE
Notary Public - State of Florida
Commission # HH 654358
My Comm. Expires Mar 20, 2029
Bonded through National Notary Assn.

(Seal)

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Mail order	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Gifthealth Pharmacy AZ

Physical Address: 4008 S Signal Butte Rd Ste 101

City: Mesa State: AZ Zip: 85212

Mailing Address (if different from physical address): 266 N 4th St Ste 200

City: Columbus State: OH Zip: 43215

Telephone: 8336144438 Toll Free # (NAC 639.708, NRS 639.23286): 8336144438

Fax: 8332811591 Contact Email: gpaz@gifthealth.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Devin Alexander

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24973

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Devin Alexander	NV Pharmacist Registration #: 24973
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Eir GH MIDCO, LLC

Corporation/Organization Name: Gifthealth, INC.

Mailing Address: 266 N 4th St Ste 200

City: Columbus State: OH Zip: 43215

Telephone: 8336144438 Email: acadia@gifthealth.com

Contact Person Name: Acadia Gaver

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Gifthealth Pharmacy AZ (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

John Romano

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/29/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, John Romano hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Gifthealth Pharmacy AZ (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

John Romano

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 29th day of October, 2025

Notary Public

NOTARY PUBLIC STATE OF OHIO

ACADIA GAVER
Notary Public
State of Ohio
My Comm. Expires
September 19, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Romano

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/29/25
Date

Board Use Only	Date Received: 11/1/25	Amount: $500 CK 5171

Ownership

Gifthealth, INC. owns 100% of Gifthealth Pharmacy AZ, located at 4008 S. Signal Butte Road, Suite 101, Mesa, AZ 85212.

Eir GH MIDCO, LLC owns 100% of Gifthealth, INC., located at 266 N 4th St., Ste 200, Columbus, OH 43215.

Officers

John Romano, President & Director (Indirect Ownership)

[redacted]

Neil Vangala, Vice President & Director (No Ownership)

[redacted]

John Blakeley, Vice President & Director (No Ownership)

[redacted]

Brett Carlson, Director (No Ownership)

[redacted]

Fred Pettijohn, Director (No Ownership)

[redacted]

David Kerr, Director (No Ownership)

[redacted]

Gifthealth, INC. Subsidiaries

Gifthealth, INC. owns Gifthealth Pharmacy, located at 4343 Equity Dr., Ste A, Columbus OH 43228.

Gifthealth, INC. owns Gift Direct Pharmacy, LLC dba Gift Direct Pharmacy, located at 2300 Marilyn Park Lane Suite 3, Columbus, Ohio 43219.

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GIFTHEALTH, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF NOVEMBER, A.D. 2025.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3700294 8300

SR# 20254477831

Authentication: 205250650

Date: 11-07-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Gifthealth, INC. dba Gifthealth Pharmacy AZ

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 4008 S Signal Butte Rd Ste 101

City: Mesa State: AZ Zip: 85212

Mailing Address (if different from physical address): 266 N 4th St Ste 200

City: Columbus State: OH Zip: 43215

Telephone: 8336144438 Website:

Licensing Company Email: gpaz@gifthealth.com

Section 2: Personal Information

First: Devin Middle: Keith Last: Alexander

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pacific University Oregon		07/08 - 06/11	
Address	**City**	**State**	**Zip**
2043 College Way	Forest Groe	OR	97116
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
South Mountain College		06/06 - 05/08	
Address	**City**	**State**	**Zip**
7050 S. 24th St.	Phoenix	AZ	85042
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Mesa Community College		08/05 - 05/06	
Address	**City**	**State**	**Zip**
1833 W. Southern Ave.	Mesa	AZ	85202
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Rapid City Central HS		09/91 - 06/94	
Address	**City**	**State**	**Zip**
433 Mt. Rushmore Rd.	Rapid City	SD	57701
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/22 - Present	[redacted]			
11/17 - 09/22				
11/11 - 11/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Gifthealth			09/25 - Present
Business Address	**City**	**State**	**Zip**
4008 S. Signal Butte Rd.	Mesa	AZ	85212
Phone	**Title**		**Number of Employed Hours**
8336144438	Pharmacist in Charge		240
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Victor Medical / Exclusivet Pharmacy			06/12 - 12/24
Business Address	**City**	**State**	**Zip**
1485 S. Higley Rd Suite 102	Gilbert	AZ	85296
Phone	**Title**		**Number of Employed Hours**
877-928-3879	Director of Pharmacy PIC		23,550
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Devin Alexander, **certify that as the designated representative for**

Gifthealth, INC. dba Gifthealth Pharmacy AZ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DA I am at least 21 years of age;
3. DA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Devin Alexander

Print Name (First, Last)

Devin Alexander PharmD RPh

Original Signature (electronic, copies or stamps not accepted)

10-21-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Devin Alexander

Print Name (First, Last)

Devin Alexander PharmD RPh — 10-21-25

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Devin Alexander, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Devin Alexander PharmD RPh — 10-21-25

Original Signature — **Date**

Subscribed and Sworn to before me this 21st day of Oct, 2025.

MANMEET KAUR
Notary Public Arizona
Maricopa County
Commission # 678473
My Commission Expires January 29, 2029

Notary Public Signature

(Seal)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y010229	10/31/2026	Gifthealth Pharmacy AZ

Address :

4008 S. Signal Butte Road

Zip :	City :	State :
85212	Mesa	AZ

Phone :	Email :	Inspection Date :
(833) 614-4438	acadia@gifthealth.com	10/28/2025

PIC :	DEA # :	Inspection Reviewed With :
Devin Alexander	No DEA Registration	PIC

Inspection type :

Opening

Inspection Conducted By :

Max Jacobson

ACTIVITIES

1	Nonsterile Compounding	☐ YES	☑ NO
2	Nonsterile Hazardous Compounding	☐ YES	☑ NO
3	Sterile Compounding	☐ YES	☑ NO
4	Sterile Hazardous Compounding	☐ YES	☑ NO

Hospital Facility Data

# Licensed Beds	DHS License #

PHARMACY DEPARTMENT

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Size/Personnel 2544 sq ft.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
2	Shelves	☐ S ☑ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Design-efficient, safe pharmacy practice	☐ S ☑ C/P ☐ U ☐ N/A	R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
4	Counter	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Aisles	☐ S ☑ C/P ☐ U ☐ N/A	R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area This is a closed door facility.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(D)
7	Enclosed (barrier)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
9	Lighting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
10	Temperature controlled/Ventilation HVAC throughout. Temp and humidity are electronically monitored.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

11	Working counter barrier	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(H)
12	Receiving/checking area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(F)
14	Walls	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410(E)

SECURITY

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Controlled substances No controlled substances will be kept or dispensed.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Pharmacist access	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Additional pharmacy drug storage areas	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Therapeutics reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Drug compatibility reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Drug product equivalency reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Sterile products reference	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

6	Policy and procedure manual-pharmacy operations R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)	☑ S ☐ C/P ☐ U ☐ N/A
7	Policy and procedure manual-technicians R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)	☑ S ☐ C/P ☐ U ☐ N/A
8	Policy and procedure manual-automation R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04	☑ S ☐ C/P ☐ U ☐ N/A
9	Policy and procedure manual-compounding R4-23-410; R4-23-670	☐ S ☐ C/P ☐ U ☑ N/A
10	Arizona statutes/rules R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	☑ S ☐ C/P ☐ U ☐ N/A
11	Current antidote/drug interaction information R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	☑ S ☐ C/P ☐ U ☐ N/A
12	Poison Control # displayed R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A) Poison Control stickers were provided.	☑ S ☐ C/P ☐ U ☐ N/A

PHARMACY EQUIPMENT/FORMS

1	Refrigerator R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	☑ S ☐ C/P ☐ U ☐ N/A
2	Freezer R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A) No drug storage freezer is utilized.	☐ S ☐ C/P ☐ U ☑ N/A
3	Computer-security/data storage R4-23-408	☑ S ☐ C/P ☐ U ☐ N/A

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4	Computer-patient profiles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(3)
5	Computer-single drug usage report	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(4)
6	Computer-pharmacist log book/hard copy print out Discussed possibility of an electronic RPh log book. The PIC is still working on how to best accomplish this requirement.	☐ S ☑ C/P ☐ U ☐ N/A	R4-23-408(C)(4)
7	Prescription label	☑ S ☐ C/P ☐ U ☐ N/A	ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)
8	Federal transfer labels	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
9	Warning labels	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
10	Written patient information	☐ S ☑ C/P ☐ U ☐ N/A	R4-23-402(C)(4); R4-23-402(I)
11	Consultation log	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-402(G)
12	Federal medication guides	☑ S ☐ C/P ☐ U ☐ N/A	21 CFR part 208
13	Hospital IV label	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-658
14	Generic Rx blanks	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-402(A); R4-23-407(D)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

15	Immunization administration recordkeeping	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-411(F)
16	Schedule V register	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(2)
17	Methamphetamine precursor sales log No OTC sales.	☐ S ☐ C/P ☐ U ☑ N/A	ARS 32-1977
18	Red C stamp	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting This facility does not have a DEA registration and has no requirement to report to the CSPMP	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-502
20	Graduates	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

25	Weights for Rx balance	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device No automation was on site at this time. The PIC described various types of automation that may be deployed. Discussed SOPs and other requirements for automation.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-615
30	Mechanical counting device No automation was on site at this time. The PIC described various types of automation that may be deployed. Discussed SOPs and other requirements for automation.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-616
31	Emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size No compounding is performed.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(2)
4	Restricts entry/access	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
9	Environment ISO 7	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(6)
10	Hood ISO 5	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

Hours: 9 to 4 M-F

Best of luck on your new pharmacy!

Currently permitted the initial space with the idea
of expanding the pharmacy through remodel.

PIC is aware of the remodel application and inspection requirements.

All COMPLIANCE PENDIG issues must be resolved
prior to operation.

No controlled substances will be kept or dispensed.

Corrective Action Plan: Gifthealth

Date: 31 October 2025

Company Name: Gifthealth Pharmacy AZ
Address: 4008 S. Signal Butte Rd. Suite 101, Mesa AZ 85212

Corrective Action Plan for Compliance Pending Issues Prior to Opening

Inspector: AZ Board of Pharmacy Inspector
Return ETA: Upon notification of resolved issues below, by 21 November 2025

Issues and Corrective Actions

Issue	Corrective Action	Assigned owner	Estimated Completion Date
1. Shelves	Finishing install	Facilities Kimte	Complete 11/20/2025
2. Design Efficient Safe Pharmacy Practice	Workstation install completion	Facilities Kimte	Complete 11/20/2025
3. Aisles	Install completion	Facilities Kimte	Complete 11/20/2025
4. Computer Pharmacist Log Book	Add attestation to electronic signature book	IT Dan, Adam	Complete 11/10/2025
5. Written Patient Information	Add additional contact information electronically	IT Dan, Adam	Complete 11/12/2025

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 08/05/2025
Receipt Number: 2025199670
Receipt Amount $: 480.00

Pharmacy - Limited Service

Mail Order

PERMIT NO	EXPIRES
Y010229	10/31/2026

Issued to : Gifthealth Pharmacy AZ
Gifthealth, INC.
266 N 4TH ST SUITE 200 COLUMBUS, OH 43215

Gifthealth Pharmacy AZ
4008 S. SIGNAL BUTTE ROAD SUITE 101
MESA, AZ 85212

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Gifthealth Pharmacy AZ
LICENSE NUMBER : Y010229
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Gifthealth Pharmacy AZ
Address :	4008 S. Signal Butte Road Suite 101 Mesa AZ 85212
Registration No :	Y010229
Permit Type :	Pharmacy
Sub Type :	Limited Service
Date Issued :	10/29/2025
Expiration Date :	10/31/2026
Status :	OPEN
Discipline :	No

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260,
Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA PHARMACIST LICENSE FOR THE INDIVIDUAL LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Devin Alexander
Registration No :	S018948
Date Issued :	12/28/2011
Expiration Date :	10/31/2026
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 11/19/2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Gifthealth Pharmacy AZ

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Pending

Physical Address: 4008 S Signal Butte Rd Ste 101

City: Mesa State: AZ Zip: 85212

Mailing Address (if different from physical address): 266 N 4th St Ste 200

City: Columbus State: OH Zip: 43215

Telephone: 8336144438 Website:

Licensing Company Email: acadia@gifthealth.com

Section 2: Personal Information

First: John Middle: David Last: Romano

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
West Virginia University		2004-2007	
Address	**City**	**State**	**Zip**
PO Box 6201	Morgantown	WV	26500
Diploma/Degree obtained, if any			
Bachelor of Science Degree			

School Name		From - To (MM/YY – MM/YY)	
Robert C Byrd High School		1998-2002	
Address	**City**	**State**	**Zip**
1 Eagle Way	Clarksburg	WV	26301
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016-Present	[redacted]			
2012-2016				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Gifthealth, INC.			2020-Present	
Business Address		**City**	**State**	**Zip**
266 N. 4th St. Suite 200		Columbus	OH	43215
Phone	**Title**			
833-614-4438	President			
Description of Duties				
Operations				

Business Name			From - To (MM/YY – MM/YY)	
American Pharmaceutical Ingredients LLC			2022-2025	
Business Address		**City**	**State**	**Zip**
6650 Highland Road		Waterford	MI	48327
Phone	**Title**			
888-872-3243	President			
Description of Duties				
Working to build innovation in the pharmacy and PBM space, in an effort to positvely impact patients and the entire ecosystem.				

Business Name			From - To (MM/YY – MM/YY)	
ScriptDrop			2018-2020	
Business Address		**City**	**State**	**Zip**
855 Grandview Ave #110		Columbus	OH	43215
Phone	**Title**			
800-376-7715	Business Development			
Description of Duties				
Sales				

Business Name			From - To (MM/YY – MM/YY)	
Braintree Labs			2012-2018	
Business Address		**City**	**State**	**Zip**
60 Columbian Rd.		Braintree	MA	02184
Phone	**Title**			
N/A	Sales Trainer			
Description of Duties				
Sales trainer				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Romano

Print Name (First, Last)

John Romano

Original Signature (electronic, copies or stamps not accepted)

10/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, John Romano, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

John Romano

Original Signature

10/29/25

Date

Subscribed and Sworn to before me this 29th day of Oct 2025.

Notary Public Signature

ACADIA GAVER
Notary Public
State of Ohio
My Comm. Expires
September 19, 2026

(Seal)

Gifthealth, INC. dba Gifthealth Pharmacy AZ, located at 4008 S Signal Butte Road, Suite 101, Mesa, AZ 85212, does not hold a DEA registration, as the facility does not purchase, store, or dispense controlled substances.

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	■ Service Modification*	☐ Nuclear	DEA #: FH7188875
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	■ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 03867		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Honeybee Health, Inc.d/b/a Honeybee Health

Physical Address: 3515 Helms Avenue

City: Culver City State: CA Zip: 90232

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): 833-466-3979

Fax: _____ Contact Email: jessica@honeybeehealth.com

Website: www.honeybeehealth.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jessica Nouhavandi

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24887

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jessica Nouhavandi	NV Pharmacist Registration #: 24887
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): N/A

Corporation/Organization Name: Honeybee Health, Inc.

Mailing Address: 3515 Helms Ave

City: Culver City State: CA Zip: 90232

Telephone: 805-990-8555 Email: jessica@honeybeehealth.com

Contact Person Name: Jessica Nouhavandi

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ■ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Supervising/Managing RPh (title) for Honeybee Health Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jessica Nouhavandi

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1-19-26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jessica Nouhavandi hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Supervising/Managing RPh (title) for Jessica Nouhavandi (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

jnouhavandi
Signature

State of California County of Los Angeles

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19th day of January, 2026

Notary Public Adam S. Goldman

ADAM S. GOLDMAN
Notary Public - California
Los Angeles County
Commission # 2476626
My Comm. Expires Jan 13, 2028

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Nouhavandi

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1-19-26

Date

Board Use Only	Date Received: 1/22/26	Amount: 500.00 / V# 3075

Honeybee Health, Inc.

Question:

Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

Response: Yes

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Idaho – case #BOP-21-076. On August 26, 2021, Honeybee received a fully executed Stipulation and Consent Order from the State of Idaho. Honeybee agreed to discipline for not maintaining a properly registered Idaho pharmacist-in-charge. Honeybee paid a penalty in the amount of $4,000.

Hawaii (reciprocal) – case #PHA-2021-49-L. On February 17, 2022, Honeybee received a fully executed Settlement Agreement. Honeybee agreed to pay a penalty of $500 for earlier discipline imposed by the Idaho State Board of Pharmacy.

Arizona – case #22-0012. On June 23, 2022, Honeybee received an Order for Non-Disciplinary Civil Penalty for Honeybee's failure to report the Idaho Stipulation and Consent Order on the pharmacy's Arizona renewal application. Honeybee paid a penalty in the amount of $250.

Jessica Nouhavandi
Pharmacist in Charge, COO, and Shareholder Honeybee Health, Inc.

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the Registration of:	)	
	)	Case No. BOP- 21-076
HONEYBEE HEALTH, INC.	)	
	)	**STIPULATION AND CONSENT**
Registration No. 47790MS	)	**ORDER**
	)	
Respondent.	)	
	)	

WHEREAS, information has been received by the Idaho Board of Pharmacy (the "Board"), that constitutes sufficient grounds for the initiation of an administrative action against HONEYBEE HEALTH, INC., ("Respondent"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board; now, therefore,

IT IS HEREBY STIPULATED AND AGREED between the undersigned parties that this matter shall be settled and resolved upon the terms and conditions set forth herein.

A. SUMMARY OF THE STIPULATED DISCIPLINE

A.1. Respondent acknowledges and admits that it violated the Board's laws and rules when it: failed to maintain a properly registered nonresident PIC between July 1, 2018, and December 29, 2020, during which time Respondent dispensed 1,440 prescriptions to Idaho without a registered nonresident PIC.

A.2. In lieu of a formal disciplinary hearing, Respondent agrees to pay a fine in the amount of **$4,000 on or before October 27, 2021.** This date is 60 days after the next scheduled Board meeting, at which time this Stipulation will be presented for approval. Respondent understands that the Board must approve this Stipulation before payment can be sent.

B. JURISDICTION OF THE BOARD

B.1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code and the Board rules promulgated at IDAPA 24.36.01, *et seq.* (formerly IDAPA 27.01.01, *et seq.*). The Board is further empowered by title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 24.36.01, *et seq.* (formerly IDAPA 27.01.01, *et seq.*) to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

B.2. Respondent is a licensee of the Board and holds an Out of State Mail Service Pharmacy Registration No. 47790MS, and therefore is subject to the provisions of title 54, chapter 17, Idaho Code; title 37, chapter 27, Idaho Code; and the Board's rules promulgated at IDAPA 24.36.01, *et seq.* (formerly IDAPA 27.01.01 *et seq.*).

C. STIPULATED FACTS

C.1. Respondent is an Out of State Mail Service Pharmacy doing business in Culver City, CA, and holding Registration No. 47790MS, initially issued on March 29, 2018, and expiring on December 31, 2021.

C.2. On December 17, 2020, Respondent attempted to renew its Out of State Mail Service Registration. Board staff discovered that Respondent was operating in Idaho without a registered nonresident PIC. Respondent had a designated nonresident PIC who was not registered in Idaho as required under Idaho law and Board rules, since June 30, 2018.

C.3. On December 31, 2020, Board staff sent Respondent an investigatory letter requesting a list of prescriptions that were sent to Idaho through Respondent between July 1, 2018, and December 29, 2020.

C.4. On January 11, 2021, Respondent emailed a response to the investigatory letter and

provided some, but not all, of the requested information. The records provided by Respondent show that between February 28, 2019, and December 29, 2020, Respondent sent 1,440 to Idaho without a registered nonresident PIC.

C.5. Idaho law and Board rules require a nonresident facility to have a PIC who is registered by the Board. Also, a nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be registered to practice into Idaho. By operating without a registered nonresident PIC from June 30, 2018 to December 29, 2020, Respondent has violated I.C. § 54-1729(1)(a); and 24.36.01.210.02 (03-20-20) (formerly IDAPA 27.01.02.030.02(b) (04-01-19) and IDAPA 27.01.01.210.02 (07-01-18).

C.6. Respondent acknowledges its actions constituted violations of the statutes and rules governing the practice of pharmacy in Idaho. More specifically, Respondent admits the violations are subject to the following statutes and rules:

a. Idaho Code § 54-1726(1)(f) (Grounds for Discipline. The Board may suspend, revoke or restrict the registration of any person, upon one or more of the following grounds ... being found by the Board to be in violation of any of the provisions of this chapter, chapter 27, title 37, or rules adopted pursuant to either chapter.);

b. Idaho Code § 54-1728(1)(f) (Penalties and Reinstatement. Upon finding the existence of grounds for discipline, the Board may impose one or more of the following penalties ... imposition of an administrative fine not to exceed $2,000 for each occurrence providing a basis for discipline.);

c. Idaho Code § 37-2718(a)(4) (Discipline. The Board may suspend, revoke or restrict a registration upon a finding that the registrant...has violated this chapter or any rule of the Board promulgated under this act);

d. Idaho Code § 37-2719(c) (...upon a finding of grounds for restriction, suspension or revocation, the Board may also impose an administrative fine not to exceed $2,000 per occurrence and the costs of prosecution and administrative costs including, but not limited to, attorney's fees and costs.);

e. Idaho Code § 54-1729(1)(a) (All drug or device outlets doing business in or into Idaho shall: (a) If a nonresident, be licensed or registered and in good standing in the applicant's state of residence and, if a pharmacy, have a PIC who is registered by the board...); and

f. IDAPA 24.36.01.210.02 (03-20-20); (formerly IDAPA 27.01.02.030.02(b) (04-01-19); and IDAPA 27.01.01.210.02 (07-01-18)) (A nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be registered to practice into Idaho.); and

C.7. In lieu of proceeding with a formal disciplinary hearing, Respondent hereby agrees the Board may enter a final order against its Registration as set forth in Section D below.

D. STIPULATED PENALTIES

D.1. The parties agree that, under the facts presented and the regulations that apply to such facts, the Board has the authority pursuant to Idaho Code § 54-1728(f) and Idaho Code § 37-2719(c) to impose an administrative fine of $2,000 per occurrence for operating without a registered PIC and sending 1,440 prescriptions into Idaho while unauthorized and unregistered to do so. However, to resolve this matter, it is agreed that Respondent shall pay a fine in the amount of $4,000 for the violations outlined in Section C above. This fine shall come due only after the Board approves and executes the Order incorporating this Stipulation and shall be paid to the Board October 27, 2021. This is 60 days after the date of the next scheduled Board

meeting. Respondent understands that the Board must approve this stipulation before payment can be sent;

D.2. Failure to comply with any of the terms of this Stipulation and Consent Order may result in additional disciplinary action being taken against Respondent;

D.3. All costs associated with Respondent's compliance with the terms of this Stipulation and Consent Order shall be solely the responsibility of Respondent.

E. COMPLIANCE WITH STIPULATION AND CONSENT ORDER

E.1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondent has violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent, and its attorney, if applicable, that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not file an answer to the administrative complaint, all allegations of non-compliance will be deemed admitted and default may be entered against Respondent;

E.2. If Respondent fails to comply with this Stipulation, Respondent's registration may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section;

E.3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be the sole responsibility of the Respondent.

F. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

F.1. Respondent admits to the allegations stated above in Section C. Respondent understands these allegations constitute cause for disciplinary action upon its Registration;

F.2. Respondent agrees the Board has jurisdiction to proceed in this matter with its consent as indicated by signature of Respondent's authorized representative hereto;

F.3. Respondent's authorized representative has read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondent understands and acknowledges that by the terms set forth herein, Respondent is waiving certain rights provided under Idaho law;

F.4. Respondent understands that it has, among other rights, the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify on its own behalf; the right to reconsideration; the right to appeal this matter to district court; all rights provided by the Idaho Administrative Procedure Act; and the laws and rules governing the practice of pharmacy in Idaho. Respondent hereby freely and voluntarily waives these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein;

F.5. Respondent understands that in entering into this Stipulation, it is enabling the Board to impose disciplinary action upon Respondent's Registration as set forth in Section D, without further process;

F.6. Respondent understands the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. Respondent understands that, if approved as proposed, the Board will execute and issue this Stipulation and Consent Order according to the

aforementioned terms, and Respondent hereby agrees to the above Stipulation for settlement. If the Board approves this Stipulation subject to changes, and those changes are acceptable, Respondent acknowledges the Stipulation will take effect, and an order modifying the terms of the Stipulation will be issued. If the changes are unacceptable or the Board rejects this Stipulation, this Stipulation will be of no effect. Admissions in negotiations preceding the signing of this Stipulation will not be admissible at any subsequent disciplinary hearing;

F.7. In the event this Stipulation is rejected by the Board or any changes proposed by the Board are not accepted, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative complaint based on the fact that the Board has considered and rejected this Stipulation;

F.8. Respondent understands the Board shall have the right to make full disclosure of this Stipulation and Consent Order as necessary to comply with any reporting requirement(s) imposed on the Board by federal or any state law, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code;

F.9. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a public record;

F.10. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or otherwise, for resolution of the allegations set forth herein;

F.11. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director of the Board and the Deputy Attorney General responsible for prosecution before the Board, at the next regularly-scheduled meeting of the Board;

F.12. Except for paragraph F.6., which becomes effective when Respondent's authorized

representative signs this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board, and a Board member signs the attached Order.

DATED this 24 day of June, 2021.

(Signature- Authorized Representative)

Jessica Nouhavandi
(Print Name)
Representative on behalf of Respondent

I concur in this Stipulation and Consent Order and recommend that the Board adopt the same.

DATED this 30th day of June, 2021.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

/s/ Dayton P. Reed

Dayton P. Reed
Deputy Attorney General

I also concur in this Stipulation and Consent Order and recommend the Board adopt the same.

DATED this 6th day of July, 2021.

IDAHO BOARD OF PHARMACY

Nicole Chopski

Nicole Chopski, PharmD
Executive Director

ORDER

Pursuant to Idaho Code §§ 54-1728 and 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order and incorporates them into this Order; and it is hereby ORDERED that Respondent comply with such terms and conditions.

DATED this 26 day of August, 2021.

~~Kristina~~ Jonas, ~~PharmD~~ Richard de Betaguicre PharmD
Board Chair

CERTIFICATE OF SERVICE

I certify that on this 24 day of August, 2021, I caused to be served a true and correct copy of the foregoing to be served by the method(s) indicated below and addressed to the following parties:

Jessica Nouhavandi
3515 Helms Ave.
Culver City, CA 90232
jessica@honeybeehealth.com

- [x] U.S. Mail, Postage Prepaid
- [x] Certified Mail, Return Receipt
- [ ] Hand Delivery
- [ ] Other:
- [ ] Email: jessica@honeybeehealth.com

Dayton P. Reed
Deputy Attorney General
Civil Litigation Division
PO Box 83720
Boise, ID 83720-0010
Dayton.reed@ag.idaho.gov

- [ ] U.S. Mail, Postage Prepaid
- [ ] Certified Mail, Return Receipt
- [ ] Hand Delivery
- [ ] Other:
- [x] Email: dayton.reed@ag.idaho.gov
  penny.wilcox@ag.idaho.gov

Idaho Board of Pharmacy

STACIA M. SILVA 6760
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: (808) 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

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AND CONSUMER AFFAIRS

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HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of HONEYBEE HEALTH, INC., Respondent.	PHA 2021-49-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s) and Respondent HONEYBEE HEALTH, INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy (hereinafter the "Board") under miscellaneous permit number PMP 1487. The permit was issued on or about February 23, 2018. The permit is set to expire or forfeit on or about December 31, 2023.

2. Respondent's mailing address for purposes of this action is 3515 Helms Avenue, Culver City, California 90232.

3. On or about August 26, 2021, Respondent entered into a Stipulation and Consent Order with the Idaho Board of Pharmacy in Case No. BOP-21-076 (hereinafter the "Consent Order"). A copy of the Consent Order is attached hereto as Exhibit "1". The Consent Order was

I HEREBYCERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

based on allegations that Respondent failed to maintain a properly registered non-resident pharmacist in charge from July 1, 2018 to December 29, 2020. Respondent was issued a $4,000.00 fine.

4. RICO alleges Respondent was disciplined by the State of Idaho.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute: Hawaii Revised Statutes (hereinafter "HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein permitted as a miscellaneous permit holder by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent further understands that RICO enters into this Settlement Agreement, and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

6. Respondent represents Exhibit "1" is a true and correct copy of the Consent Order.

7. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

8. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

9. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

10. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2021-49-L.

11. Respondent acknowledges that upon its approval, this Settlement Agreement constitutes disciplinary action and understands that this Settlement Agreement may be subject to reporting requirements.

12. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of FIVE HUNDRED AND NO/100 DOLLARS ($500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Stacia M. Silva, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's miscellaneous permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

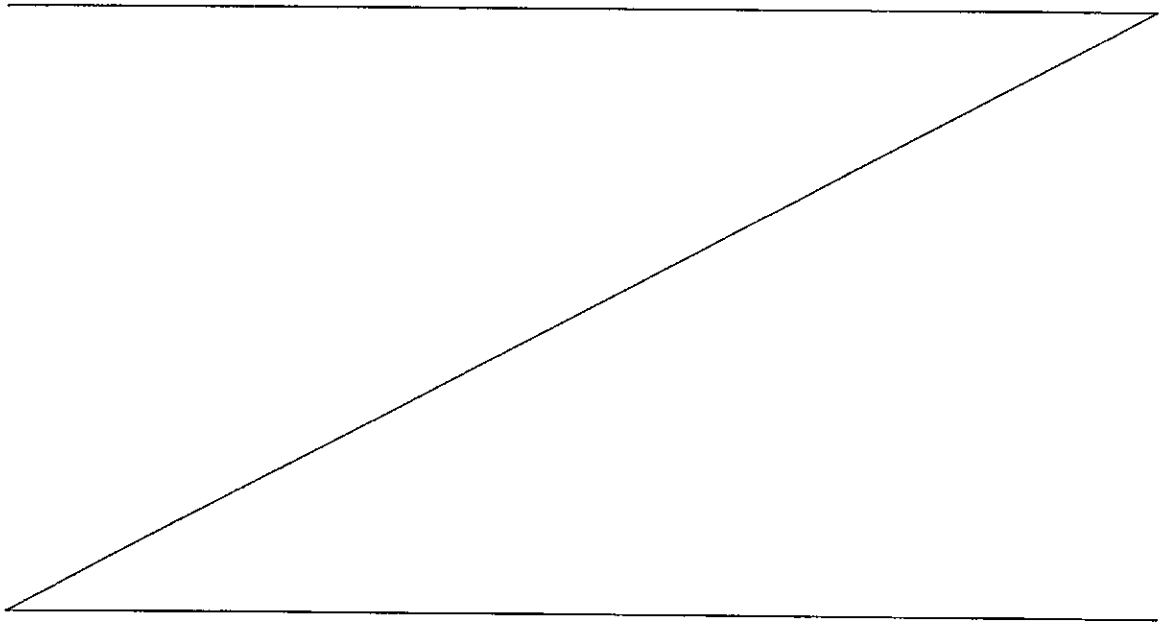
4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., C.7., and C.8. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.



IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Culver City (City), California (State), 1/21/22 (Date).

HONEYBEE HEALTH, INC.
Respondent

By: _____
(Signature)

Jessica Nouhavandi
(Print Name)

Its PIC
(Print Title)

DATED: Honolulu, Hawaii, JAN 27 2022.

_____
STACIA M. SILVA
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF HONEYBEE HEALTH, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"; RICO CASE NO. PHA 2021-49-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

	2/10/22
ALANNA ISOBE Chairperson	DATE
Julie Takishima-Lacasa, PhD	
JULIE YURIE TAKISHIMA-LACASA Vice Chairperson	PATRICK ADAMS
Mark Brown	
MARK BROWN	CATALINA CROSS
Kent Kikuchi	Sheri Tokumaru
KENT KIKUCHI	SHERI TOKUMARU

PVL 7/6/21

BEFORE THE BOARD OF PHARMACY
STATE OF IDAHO

In the Matter of the Registration of:	)	
	)	Case No. BOP- 21-076
HONEYBEE HEALTH, INC.	)	
	)	**STIPULATION AND CONSENT**
Registration No. 47790MS	)	**ORDER**
	)	
Respondent.	)	
	)	

WHEREAS, information has been received by the Idaho Board of Pharmacy (the "Board"), that constitutes sufficient grounds for the initiation of an administrative action against HONEYBEE HEALTH, INC., ("Respondent"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board; now, therefore,

IT IS HEREBY STIPULATED AND AGREED between the undersigned parties that this matter shall be settled and resolved upon the terms and conditions set forth herein.

A. SUMMARY OF THE STIPULATED DISCIPLINE

A.1. Respondent acknowledges and admits that it violated the Board's laws and rules when it: failed to maintain a properly registered nonresident PIC between July 1, 2018, and December 29, 2020, during which time Respondent dispensed 1,440 prescriptions to Idaho without a registered nonresident PIC.

A.2. In lieu of a formal disciplinary hearing, Respondent agrees to pay a fine in the amount of **$4,000 on or before October 27, 2021.** This date is 60 days after the next scheduled Board meeting, at which time this Stipulation will be presented for approval. Respondent understands that the Board must approve this Stipulation before payment can be sent.

EXHIBIT "1"

B. JURISDICTION OF THE BOARD

B.1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code and the Board rules promulgated at IDAPA 24.36.01, *et seq.* (formerly IDAPA 27.01.01, *et seq.*). The Board is further empowered by title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 24.36.01, *et seq.* (formerly IDAPA 27.01.01, *et seq.*) to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

B.2. Respondent is a licensee of the Board and holds an Out of State Mail Service Pharmacy Registration No. 47790MS, and therefore is subject to the provisions of title 54, chapter 17, Idaho Code; title 37, chapter 27, Idaho Code; and the Board's rules promulgated at IDAPA 24.36.01, *et seq.* (formerly IDAPA 27.01.01 *et seq.*).

C. STIPULATED FACTS

C.1. Respondent is an Out of State Mail Service Pharmacy doing business in Culver City, CA, and holding Registration No. 47790MS, initially issued on March 29, 2018, and expiring on December 31, 2021.

C.2. On December 17, 2020, Respondent attempted to renew its Out of State Mail Service Registration. Board staff discovered that Respondent was operating in Idaho without a registered nonresident PIC. Respondent had a designated nonresident PIC who was not registered in Idaho as required under Idaho law and Board rules, since June 30, 2018.

C.3. On December 31, 2020, Board staff sent Respondent an investigatory letter requesting a list of prescriptions that were sent to Idaho through Respondent between July 1, 2018, and December 29, 2020.

C.4. On January 11, 2021, Respondent emailed a response to the investigatory letter and

provided some, but not all, of the requested information. The records provided by Respondent show that between February 28, 2019, and December 29, 2020, Respondent sent 1,440 to Idaho without a registered nonresident PIC.

C.5. Idaho law and Board rules require a nonresident facility to have a PIC who is registered by the Board. Also, a nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be registered to practice into Idaho. By operating without a registered nonresident PIC from June 30, 2018 to December 29, 2020, Respondent has violated I.C. § 54-1729(1)(a); and 24.36.01.210.02 (03-20-20) (formerly IDAPA 27.01.02.030.02(b) (04-01-19) and IDAPA 27.01.01.210.02 (07-01-18).

C.6. Respondent acknowledges its actions constituted violations of the statutes and rules governing the practice of pharmacy in Idaho. More specifically, Respondent admits the violations are subject to the following statutes and rules:

a. Idaho Code § 54-1726(1)(f) (Grounds for Discipline. The Board may suspend, revoke or restrict the registration of any person, upon one or more of the following grounds ... being found by the Board to be in violation of any of the provisions of this chapter, chapter 27, title 37, or rules adopted pursuant to either chapter.);

b. Idaho Code § 54-1728(1)(f) (Penalties and Reinstatement. Upon finding the existence of grounds for discipline, the Board may impose one or more of the following penalties ... imposition of an administrative fine not to exceed $2,000 for each occurrence providing a basis for discipline.);

c. Idaho Code § 37-2718(a)(4) (Discipline. The Board may suspend, revoke or restrict a registration upon a finding that the registrant...has violated this chapter or any rule of the Board promulgated under this act);

d. Idaho Code § 37-2719(c) (...upon a finding of grounds for restriction, suspension or revocation, the Board may also impose an administrative fine not to exceed $2,000 per occurrence and the costs of prosecution and administrative costs including, but not limited to, attorney's fees and costs.);

e. Idaho Code § 54-1729(1)(a) (All drug or device outlets doing business in or into Idaho shall: (a) If a nonresident, be licensed or registered and in good standing in the applicant's state of residence and, if a pharmacy, have a PIC who is registered by the board...); and

f. IDAPA 24.36.01.210.02 (03-20-20); (formerly IDAPA 27.01.02.030.02(b) (04-01-19); and IDAPA 27.01.01.210.02 (07-01-18)) (A nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be registered to practice into Idaho.); and

C.7. In lieu of proceeding with a formal disciplinary hearing, Respondent hereby agrees the Board may enter a final order against its Registration as set forth in Section D below.

D. STIPULATED PENALTIES

D.1. The parties agree that, under the facts presented and the regulations that apply to such facts, the Board has the authority pursuant to Idaho Code § 54-1728(f) and Idaho Code § 37-2719(c) to impose an administrative fine of $2,000 per occurrence for operating without a registered PIC and sending 1,440 prescriptions into Idaho while unauthorized and unregistered to do so. However, to resolve this matter, it is agreed that Respondent shall pay a fine in the amount of $4,000 for the violations outlined in Section C above. This fine shall come due only after the Board approves and executes the Order incorporating this Stipulation and shall be paid to the Board ...mber 27, 2021. This is 60 days after the date of the next scheduled Board

meeting. Respondent understands that the Board must approve this stipulation before payment can be sent;

D.2. Failure to comply with any of the terms of this Stipulation and Consent Order may result in additional disciplinary action being taken against Respondent;

D.3. All costs associated with Respondent's compliance with the terms of this Stipulation and Consent Order shall be solely the responsibility of Respondent.

E. COMPLIANCE WITH STIPULATION AND CONSENT ORDER

E.1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondent has violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent, and its attorney, if applicable, that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not file an answer to the administrative complaint, all allegations of non-compliance will be deemed admitted and default may be entered against Respondent;

E.2. If Respondent fails to comply with this Stipulation, Respondent's registration may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section;

E.3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be the sole responsibility of the Respondent.

F. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

F.1. Respondent admits to the allegations stated above in Section C. Respondent understands these allegations constitute cause for disciplinary action upon its Registration;

F.2. Respondent agrees the Board has jurisdiction to proceed in this matter with its consent as indicated by signature of Respondent's authorized representative hereto;

F.3. Respondent's authorized representative has read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondent understands and acknowledges that by the terms set forth herein, Respondent is waiving certain rights provided under Idaho law;

F.4. Respondent understands that it has, among other rights, the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify on its own behalf; the right to reconsideration; the right to appeal this matter to district court; all rights provided by the Idaho Administrative Procedure Act; and the laws and rules governing the practice of pharmacy in Idaho. Respondent hereby freely and voluntarily waives these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein;

F.5. Respondent understands that in entering into this Stipulation, it is enabling the Board to impose disciplinary action upon Respondent's Registration as set forth in Section D, without further process;

F.6. Respondent understands the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. Respondent understands that, if approved as proposed, the Board will execute and issue this Stipulation and Consent Order according to the

aforementioned terms, and Respondent hereby agrees to the above Stipulation for settlement. If the Board approves this Stipulation subject to changes, and those changes are acceptable, Respondent acknowledges the Stipulation will take effect, and an order modifying the terms of the Stipulation will be issued. If the changes are unacceptable or the Board rejects this Stipulation, this Stipulation will be of no effect. Admissions in negotiations preceding the signing of this Stipulation will not be admissible at any subsequent disciplinary hearing;

F.7. In the event this Stipulation is rejected by the Board or any changes proposed by the Board are not accepted, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative complaint based on the fact that the Board has considered and rejected this Stipulation;

F.8. Respondent understands the Board shall have the right to make full disclosure of this Stipulation and Consent Order as necessary to comply with any reporting requirement(s) imposed on the Board by federal or any state law, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code;

F.9. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a public record;

F.10. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or otherwise, for resolution of the allegations set forth herein;

F.11. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director of the Board and the Deputy Attorney General responsible for prosecution before the Board, at the next regularly-scheduled meeting of the Board;

F.12. Except for paragraph F.6., which becomes effective when Respondent's authorized

representative signs this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board, and a Board member signs the attached Order.

DATED this 24 day of June, 2021.

(Signature- Authorized Representative)

Jessica Nouhavandi
(Print Name)
Representative on behalf of Respondent

I concur in this Stipulation and Consent Order and recommend that the Board adopt the same.

DATED this 30th day of June, 2021.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

/s/ Dayton P. Reed

Dayton P. Reed
Deputy Attorney General

I also concur in this Stipulation and Consent Order and recommend the Board adopt the same.

DATED this 6th day of July, 2021.

IDAHO BOARD OF PHARMACY

Nicole Chopski

Nicole Chopski, PharmD
Executive Director

ORDER

Pursuant to Idaho Code §§ 54-1728 and 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order and incorporates them into this Order; and it is hereby ORDERED that Respondent comply with such terms and conditions.

DATED this 11 day of August, 2021.

~~Kristina Jonas, PharmD~~ Richard de Bragaire PharmD
Board Chair

CERTIFICATE OF SERVICE

I certify that on this 24 day of August, 2021, I caused to be served a true and correct copy of the foregoing to be served by the method(s) indicated below and addressed to the following parties:

Jessica Nouhavandi
3515 Helms Ave.
Culver City, CA 90232
jessica@honeybeehealth.com

- [x] U.S. Mail, Postage Prepaid
- [x] Certified Mail, Return Receipt
- [ ] Hand Delivery
- [ ] Other:
- [ ] Email: jessica@honeybeehealth.com

Dayton P. Reed
Deputy Attorney General
Civil Litigation Division
PO Box 83720
Boise, ID 83720-0010
Dayton.reed@ag.idaho.gov

- [ ] U.S. Mail, Postage Prepaid
- [ ] Certified Mail, Return Receipt
- [ ] Hand Delivery
- [ ] Other:
- [x] Email: dayton.reed@ag.idaho.gov
  penny.wilcox@ag.idaho.gov

Idaho Board of Pharmacy

Arizona State Board of Pharmacy
Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749 www.azpharmacy.gov

June 23, 2022

Honeybee Health, Inc.
3515 HELMS AVE
CULVER CITY, CA 90232

Re: Board Case No. 22-0012

Dear Permit Holder,

The enclosed Order for Non-Disciplinary Civil Penalty ("Order") has been issued to you to resolve Board Case No. 22-0012. The Order specifies the conduct that resulted in the issuance of the Order. It also includes information regarding the civil penalties assessed. Please review the enclosed order carefully, as it includes the amount due and the time allowed to pay the penalty. If you fail to pay the civil penalty in the time allowed, Board staff will open a complaint against your permit for violation of a Board Order.

To pay your penalty, send a check or money order for the appropriate amount to the above mailing address. Please make your check or money order payable to the Arizona State Board of Pharmacy. To ensure that you receive credit for your payment, please ensure that your name and case number are listed on your check or money order.

This Order may be subject to appeal within 35 days of the issuance of the Order under the Board's Statutes and rule. If you wish to appeal the Order, you must submit a written request to appear before the Board at a public meeting. The Board meeting schedule is available on the Board's website.

If you have any questions regarding this notice, please contact Jennifer Mitchell, Executive Staff Assistant at (602) 771-2761 or jmitchell@azpharmacy.gov.

Sincerely,

Kam Gandhi

Kam Gandhi, PharmD
Executive Director

KG/jcm

Enclosure

Arizona State Board of Pharmacy

Physical Address: 1616 W. Adams St., Suite #120, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
Phone: 602-771-2727 Fax: 602-771-2749 pharmacy.az.gov

Order for Non-Disciplinary Civil Penalty

In the Matter of:

Respondent Name	Honeybee Health, Inc.
License/Permit No.	Y007482
Board Case No.	22-0012

	Check all that apply:			Fine(s)
☐	Failing to submit a remodel application before remodeling a permitted facility.			$250
☐	Failing to provide notice before a business is relocated.			$500
☐	Failing to update contact information within 10 days.			$50
☐	Failing to update change of employment information within 10 days.			$50
☐	Failing to complete required continuing education for pharmacist. (First offense)	Deficient CEs:		$100/CE
☐	Failing to complete required continuing education for pharmacist. (Second offense)	Deficient CEs:		$150/CE
☐	Failing to complete required continuing education for technician. (First offense)	Deficient CEs:		$25/CE
☐	Failing to complete required continuing education for technician. (Second offense)	Deficient CEs:		$37.50/CE
☐	Failing to provide notice of a new pharmacist in charge within 14 days.			$100
☐	Failing to provide notice of a new designated representative within 10 days.			$100
☐	Failing to provide notice of a new criminal charge, arrest, or conviction in any jurisdiction.			$250
☐	Failing to provide notice of disciplinary action taken against the licensee or permittee in any jurisdiction.			$250
☐	Failing to renew a pharmacist license timely within 60 days and continuing to work with an expired license.*	Days worked:		$100/day
☐	Failing to renew a technician license timely within 60 days and continuing to work with an expired license. **	Days worked:		$50/day
☐	Failing to conduct a controlled substance inventory when there is a new pharmacist in charge within 10 days.			$250
☐	Failing to obtain a permit before shipping into Arizona anything for which a permit is required.			$100/Item
☐	Failing to respond timely to a subpoena.			$50
☐	Failing to provide notice before there is a change in ownership.			$250
☐	Failing to conduct required controlled substance inventories.			$250
☒	Knowingly filing with the board any application, renewal or other document that contains false or misleading information.			$250
☐				
			TOTAL:	$250
*Max $1,000				
**Max $500				
For Office Use Only				
Comment:				

The non-disciplinary civil penalty shall be paid within 90 days from the date of issuance of this order. Failure to pay the non-disciplinary civil penalty within 90 days from date of issuance of this order shall result in this case being presented to the Board and may be subject to disciplinary action. If the licensee/permittee wishes to request a rehearing/review of the Order, the request shall be filed within 35 days of the issuance of the Order under the Board's Statutes and rule.

Payment can be made using check or money order to: Arizona State Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005

Executive Director's Signature: Kam Gandhi **Issue Date:** June 23, 2022

Honeybee Health, Inc.
Nevada Application
Permit #03867

Personal and Professional History Question 3.

Have you been the subject of a board citation or an administrative action whether completed or pending in any state?

Answer: Yes.

Alabama – Case No. 22-L-0254. On November 16, 2023, Ms. Nouhavandi received a fully executed copy of the Agreement with the Alabama State Board of Pharmacy to informally resolve pending charges against Ms. Nouhavandi. Under the Agreement Ms. Nouhavandi's reciprocity pharmacist license application was granted. Ms. Nouhavandi agreed to pay administrative costs in the amount of $500.

Jessica Nouhavandi
Pharmacist in Charge, COO, Shareholder Honeybee Health Inc.

DocuSign Envelope ID: 1BE8BEC4-2C55-49E4-91CD-CBF6C3D12D4E

DocuSign Envelope ID: DDCC438E-4C32-428B-A825-01544158402B

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
JESSICA NOUHAVANDI	)	**BOARD OF PHARMACY**
	)	
RECIPROCITY APPLICANT	)	**CASE NO: 22-L-0254**
	)	

AGREEMENT

This Agreement is entered into by and between the Alabama State Board of Pharmacy (Board) and Jessica Nouhavandi.

WHEREAS, the parties have engaged in discussions concerning an informal resolution of the Pending Charges.

WHEREAS, the parties have agreed to resolve this matter pursuant to Code of Alabama (1975) 41-22-12(f) by their approval of the following terms:

IT IS THE THEREFORE UNDERSTOOD AND AGREED BY THE PARTIES AS FOLLOWS:

1. The reciprocity pharmacist license application of Jessica Nouhavandi shall be granted.

2. As a non-disciplinary penalty, Jessica Nouhavandi shall pay administrative costs in the amount of five hundred dollars ($500) within 30 days of the final execution of this agreement. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. Jessica Nouhavandi agrees to comply with any and all of the Alabama Pharmacy Practice Act and/or any Board Rules.

4. That Jessica Nouhavandi expressly waives her rights pursuant to the Alabama Pharmacy Practice Act, and the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to Code of Alabama (1975), §34-23-92(12), Code of Alabama (1975), §41-22-12 and §41-22-20, and including but not limited to the opportunity for a hearing before the Board in connection with any charges against her and any judicial review. Jessica Nouhavandi further waives any objection to the attorney for the Board preparing, drafting, or making this Agreement, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

5. By execution of this Agreement, Jessica Nouhavandi hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Agreement and Pending Charges.

DocuSign Envelope ID: 1BE8BEC4-2C55-49E4-91CD-CBF6C3D12D4E

DocuSign Envelope ID: DDCC438E-4C32-428B-A825-01544158402B

6. Jessica Nouhavandi acknowledges and agrees that she has read this Agreement and that she fully understands the terms, conditions, and contents of the same. Jessica Nouhavandi acknowledges and agrees that she voluntarily and of her own free will accepts the terms and conditions set out in this Agreement and agrees that she is signing this Agreement on the advice of her attorney.

DONE this the 14th day of November, 2023.

Jennifer Muro Neumann
Jennifer Muro Neumann, P.C.
Post Office Box 381082
Birmingham, Alabama 35238

Robert M. Colburn, Jr., R.Ph.
President
State Board of Pharmacy

DONE this the 2nd day of November, 2023.

Jessica Nouhavandi

Michael Raine
Counsel for Jessica Nouhavandi

Honeybee Health, Inc.
3515 Helms Avenue
Culver City, CA 90232

Shareholder List:

Shareholder	Percentage of ownership[1]
Peter Wang, CEO: [redacted]	19.2%
Jessica Nouhavandi, COO: [redacted] Rey, CA	9.77%
Bullpen Capital IV, L.P: 215 2nd Street, San Francisco, CA 94110. Phone: 650-274-7830	11.42%
Susa Ventures III, L.P: 660 York St. Ste 201, San Francisco, CA 94110. Phone: 510-828-0359	8.96%
Wonder Ventures II, LP: 29500 Heathercliff Rd. #253, Malibu, CA 90265. Phone 310-910-1067	8.52%
Amplify LA Capital IV, LP. 1600 Main Street, Venice, CA 90291. Phone: 858-703-7794	5.57%
Six (6) Businesses with less than 3% ownership each	10.37%
Fifteen (15) Businesses with less than 1% ownership each	4.46%
Sixty-Nine (69) Individuals with less than 1% ownership each	15.38%
Ownership shares not yet issued	6.35%
Total:	100%

[1] Rounded to nearest one-hundredth %.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Honeybee Health, Inc.d/b/a Honeybee Health

Pharmacy/Wholesaler License # (if applicable): 03867

Physical Address: 3515 Helms Avenue

City: Culver City State: CA Zip: 90232

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 833-466-3979 Website: www.honeybeehealth.com

Licensing Company Email: jessica@honeybeehealth.com

Section 2: Personal Information

First: Jessica Middle: Sahar Last: Nouhavandi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western University of Health Sciences		2007 -- 2011	
Address	**City**	**State**	**Zip**
309 E 2nd St	Pomona	CA	91766
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
American Jewish University		2002 -- 2006	
Address	**City**	**State**	**Zip**
15600 Mulholland Dr	Los Angeles	CA	90077
Diploma/Degree obtained, if any			
Bachelor of Science in Bioethics			

School Name		From - To (MM/YY – MM/YY)	
University High School		1998-2002	
Address	**City**	**State**	**Zip**
11800 Texas Ave	Los Angeles	CA	90025
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
NA			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Honeybee Health, Inc.d/b/a Honeybee Health			09/2017-present	
Business Address		**City**	**State**	**Zip**
3515 Helms Avenue		Culver City	CA	90232
Phone	**Title**		**Number of Employed Hours**	
833-466-3979	Co-Founder, COO, and Pharmacist in Charge		Over 16,000	
Description of Duties				
Responsible for all pharmacy operations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/23/2022		AZ	Phoenix	Maricopa
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
#22-0012		Arizona Board of Pharmacy		
Reason/Charge				
Failure to report the Idaho disciplinary action				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Arizona – case #22-0012. On June 23, 2022, Honeybee received an Order for Non-Disciplinary Civil Penalty for Honeybee's failure to report the Idaho Stipulation and Consent Order on the pharmacy's Arizona renewal application. Honeybee paid a penalty in the amount of $250.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1-19-26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/17/2022		HI	Honolulu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
#PHA-2021-49-L	Hawaii Board of Pharmacy

Reason/Charge
Previous disciplinary action imposed by the Idaho Board of Pharmacy

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Honeybee Health Inc., Pharmacy

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Hawaii (reciprocal) – case #PHA-2021-49-L. On February 17, 2022, Honeybee received a fully executed Settlement Agreement. Honeybee agreed to pay a penalty of $500 for earlier discipline imposed by the Idaho State Board of Pharmacy.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1-19-26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/26/2021		ID	Boise	Ada
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
#BOP - 21- 076		Idaho Board of Pharmacy		
Reason/Charge				
Improper registration of Idaho pharmacist in charge				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Idaho – case #BOP-21-076. On August 26, 2021, Honeybee received a fully executed Stipulation and Consent Order from the State of Idaho. Honeybee agreed to discipline for not maintaining a properly registered Idaho pharmacist-in-charge. Honeybee paid a penalty in the amount of $4,000.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1-19-26
Date

I, Jessica Nouhavandi, **certify that as the designated representative for**

Honeybee Health, Inc. d/b/a Honeybee Health,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jessica Nouhavandi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-19-26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Nouhavandi

Print Name (First, Last)

jnouhavandi — 1-19-26

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Jessica Nouhavandi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

jnouhavandi — 1-19-26

Original Signature — **Date**

State of California County of Los Angeles

Subscribed and Sworn to before me this 19th day of January 2026.

Notary Public Signature Adam S. Goldman

ADAM S. GOLDMAN
Notary Public - California
Los Angeles County
Commission # 2476626
My Comm. Expires Jan 13, 2028

(Seal)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy Clinic Exempt Hospital Wholesaler Hypodermic

Date: 8/20/2024 Inspector: Huy Do

Firm: HONEYBEE HEALTH INC DBA HONEYBEE HEALTH Phone: (310) 559-5903

Address: 3515 HELMS AVE City: CULVER CITY Zip: 90232

Ownership: CORPORATION

Permit #: PHY58817 Permit Exp: 9/1/2025 DEA#: [redacted] DEA Exp: 10/31/2026

Date of Self Assessment Form: 6/30/2023 Other Permit #: N/A Date of DEA Inventory: 6/24/2024

Hours M-F: 6AM-6PM Hours Saturday 7AM-3:30PM Hours Sunday: 7AM-3:30PM

PIC **JESSICA S NOUHAVANDI** RPH66400 Administrator

RPH Consultant

Staff RPH Name:	License #:
MARC D YOUNG	RPH66291
KENT WONG	RPH73075
JIN H CHOI	RPH84191
VERENA VALENTIN V FIRP	RPH63432
PAUL D HAM	RPH80697
JAMES J KIM	RPH50525
MARK JONIFER D MARTINE	RPH82408
TANYA MORIM	RPH71895
STEVE S PHAN	RPH66670
TRANG N SON	RPH58770
KELVIN T TRUONG	RPH85484
SHUMOKH A ALANAZI	INT50769
SIMRAT KAUR	INT48602

Staff Name:	License #:
ALEJANDRA PEREZ	CLERK
AMANDA R JACKSON	TCH157976
AMBER C COLES	TCH170843
ANA K LOPEZ	TCH76841
ANTHONY GOMEZ	TCH185693
ARACELI A PLATAS	TCH186804
ARTHUR TAYLOR	CLERK
CHEYENNE R REID	TCH179787
EDGER QUIADA	CLERK
EDWARD C JOSEPH	TCH161161
ERIC MATSON	CLERK
JESSICA I CABALLEROS PA	TCH169367
LAURIN B HUNTER	TCH163742
LEWIS HALL	CLERK
MARLEN MERIDA-CRIANOS	TCH183388
PETER G WANG	TCH125618
REX C RANDELL	TCH183938
SACHI ELLER	CLERK
SHEILA DAVE	CLERK
VIOLETA G MENENDEZ	TCH140877

Inspector Remarks:

Closed door pharmacy servicing only mail order prescription licensed in all 50 states. Here today for a routine inspection and CI 2024 105264 assisted by PIC Nouhavandi.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy fills an average of 1000 RXs/day and typically staffed with 7 RPH/10TCH/6 Clerk per day. Services ranges from maintenance medications to men/womens health.

Routine Inspection:
Pharmacy with sink containing hot/cold running water and restroom located inside the pharmacy.

Medication storage: reviewed 1 fridge and 1 freezer all with temperature monitored electronically. Reviewed refrigerated medication delivery package process. Ice packs are stored in freezer and packaged with associated drugs.

Rx Label/ Rx files: Patient centered with description printed.

Self-Assessment/PHY permit/DEA registration: reviewed.

Notice to consumer sign/point to your language sign- reviewed with new poster displayed
Interpretive services provided by Language Line

Consultation: No walk in customers. Pharmacy mainly uses delivery service to mail prescriptions at provided by Fedex and USPS. Written notice of consultation printed and given to customers as prepared for delivery.

QA for med errors: Policy in place. Reviewed most recent QA report completed 7/17/2024. QA reports are hand written and also documented electronically. Educated to completed QA for all medication errors and to have records be immediately retrievable in the pharmacy and discussed new requirements for reporting medication errors.

CURES: Reviewed Zero report received daily by Bamboo Health. Discussed new requirements for reporting CURES.

DEA 222/POA/DEA 106-No CIIs ordered at the pharmacy, last ordered 6/2023. Reviewed POA. Reviewed returned/expired CII dispositions, last completed 2/27/2024. No recent drug losses.

Invoices- Reviewed. Controlled medications are Filed Separately.

DEA/CII Inventory and Reconciliation: Reviewed biennual inventory and CII quarterly reconciliation. Last completed 6/24/2024. Reviewed reconciliation for required 4 controlled substances, last completed 6/24/2024.

Security / Controlled substances- Control medications are stored in a locked cabinet. Access to cabinet given only to RPH. Only RPH has keys to pharmacy. Alarm and security cameras in use in the pharmacy. Only one entrance into/out of the pharmacy.

Records storage – all records are stored in pharmacy. No off-site waivers used.

Reviewed book of CII, CIII-CV, and legend drugs.

CAIR2 Reporting: No immunizations administered at the pharmacy
Warehouse Supplier: Cardinal/Anda/Auburn/SouthPointe
Reverse Distributor: Return Solutions

Expiration dating- spot checked inventory for expired products, pharmacy completes on a monthly basis with a 6 month window

Compound: No compounding completed at the pharmacy

Computer: Guardian Carepoint

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INSPECTION REPORT

Name tags and ratios- reviewed.

P/P: Reviewed policies for Technician Job Description, Theft/Diversion/Impairment, Temporary Absence of a Pharmacist available through License Protection Handbook.

CI 2024 105264
Reviewed incident and reviewed process for accepting prescriptions. Discussed jurisdiction and requirements for a prescription. Reviewed process for confirmation of prescription and delivery. Collected records and dispensing history.

In order to complete this inspection, please provide the following by 9/3/2024 by email at huy.do@dca.ca.gov .

1. Written Statement from PIC detailing incident

The following were discussed:

1. AB1286/CCR 1714.3 Community Pharmacy Staffing
2. CCR 1746.4 – Pharmacist initiating and administering vaccines.
3. CCR 1715.6 – Reporting drug loss.
4. CCR 1717.5 – Automatic Refill Programs.
5. CCR 1714.3- Community pharmacy staffing
6. BPC 4113.7 and CCR 4317 Prohibition on Quotas Related to Pharmacist
7. March 2024 Scripts now available on the BOP' website

Topics to Educate

1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.
   - Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.
   - Retain records for 3 years.
2. BPC 4113 – PIC authority to make staffing decisions
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:
     - Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
     - Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
     - Vermin infestation that poses a risk to the safety or efficacy of medicine.

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INSPECTION REPORT

3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.

- Applies to "community pharmacies" – *i.e.*, any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
- Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.

4. BPC 4113.6 – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:

- RPH on duty waives the requirement in writing during specified hours based on workload need.
- The pharmacy is open beyond normal business hours (*i.e.*, before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
- The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted, and included on the outgoing telephone message.

5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.

6. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

Licensee Remarks:

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INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) jnouhavandi

Pharmacist (print) Jessica Nouhavandi

Inspector (sign) [illegible]

Inspector (print) [illegible]

Owner(sign) jnouhavandi

Owner(print) Jessica Nouhavandi

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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Department of Consumer Affairs
Gavin Newsom, Governor

OFFICIAL RECEIPT

August 20, 2024

Receipt Number: 51

Firm: HONEYBEE HEALTH INC DBA HONEYBEE HEALTH

Address: 3515 HELMS AVE, CULVER CITY CA 90232

Permit #: PHY58817

Phone: (310) 559-5903

The following was obtained this date under provisions of the California Pharmacy Law (Chapter 9, Division 2, Business and Professions Code) or the Rules and Regulations adopted thereunder:

Qty	Units	Description
2	Page(s)	Copy of Rx 7292769 and Rx 7292768
1	Page(s)	SM medication profile

Voluntarily Released for Investigation

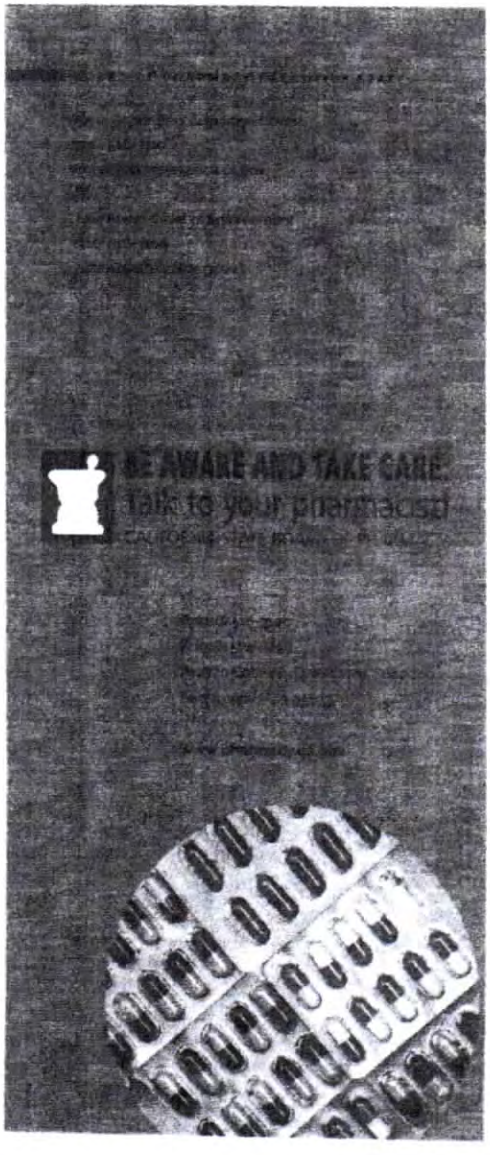
Receipt acknowledged by: _____ PIC/owner.
Title

Inspector: _____

171-6 (Rev. 3/99)

AFTER THE INSPECTION

LET US KNOW HOW WE PERFORMED



PHARMACY INSPECTIONS

BY THE CALIFORNIA STATE BOARD OF PHARMACY



WHAT YOU CAN EXPECT FROM AN INSPECTION – WHAT THE BOARD EXPECTS FROM YOU

WHAT YOU CAN EXPECT

AN INSPECTOR WILL:

- Identify himself/herself with a board-issued badge and provide a business card
- Be professional and courteous
- Provide a receipt for any records taken into possession
- Review and leave a copy of the inspection report with the pharmacist on duty and/or pharmacist-in-charge. Provide explanations and answer questions about pharmacy laws and regulations

WHAT IS EXPECTED OF YOU

PHARMACY STAFF WILL:

- Provide access to the inspector during regular business hours
- Provide access to review all stocks of dangerous drugs and devices
- Provide access to review all records of manufacture, sale, acquisition, receipt, shipment and disposition
- Allow the inspector to secure samples or specimens

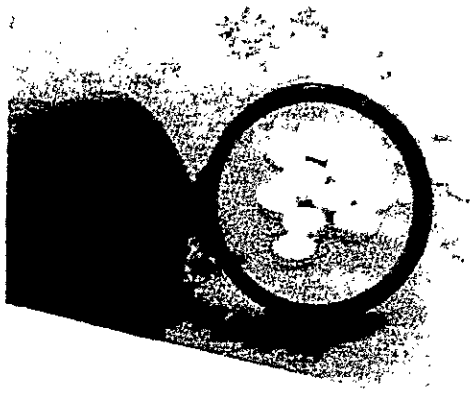


DOCUMENTS FOR INSPECTION

Pharmacies are required to have certain documents readily available for inspectors to review. Hard and electronic copies of records must be available during business hours.

DOCUMENTS TO HAVE AVAILABLE INCLUDE:

- Past inspection reports
- Pharmacy self-assessments
- Copies of staff licenses
- Master list of pharmacist and technician initials
- DEA 222 forms
- Power of attorney to execute DEA 222 forms
- DEA biennial inventory
- Drug take-back records
- Wholesaler invoices
- Records of drug returns
- Records of destruction
- Off-site records waiver
- Pedigrees for drugs purchased
- Inventory reconciliation reports
- Controlled substances refill reports
- Policies:
  - Quality assurance reports
  - QA for medication errors
  - Theft and impaired licensees
  - Pharmacy technician job description
  - Pharmacist absence for meals
  - After hours deliveries
  - Interpretive services
  - Repackaging previously dispensed drugs
  - Automated Drug Delivery Systems
  - Common electronic files to prevent unauthorized release of patient information
- Protocols:
  - Refusing to dispense on ethical, moral, religious grounds
  - Immunizations
  - Emergency contraception
  - Nicotine replacement
  - Advanced practice pharmacist
  - Procedures performed pursuant to BPC section 4052.2



ADDITIONAL ITEMS

THE INSPECTOR ALSO WILL CHECK:

- DEA registration
- Drug expiration dates
- Drug take-back receptacles
- Hot/cold running water (must be in the restroom)
- Confidential waste disposal
- Interpretive services policy
- Notice to consumers poster
- Restroom location
- Patient consultation
- Posted pharmacy license and renewal
- Out-of-state pharmacy
- Prescription labeling
- Prescription records
- Quarantine area for expired and recalled drugs
- Refrigerator/freezer temperature
- Security features
- Staffing ratio
- Transmission of CURES data
- Hearing identification [illegible] at least 18-point type
- Possession of keys to the pharmacy

honeybee

Marc Young <marc@honeybeehealth.com>

Written Statement from PIC-Please confirm receipt

1 message

Jessica Nouhavandi <jessica@honeybeehealth.com> Mon, Aug 26, 2024 at 3:05 PM
To: huy.do@dca.ca.gov
Bcc: marc@honeybeehealth.com

Hello Inspector Do,

It was a pleasure meeting you last week during our routine pharmacy inspection. Thank you for providing us with valuable feedback and keeping us informed on the most up to date BPC topics.

Regarding CI 2024 105264, please accept this email correspondence as my written statement regarding the incident related to patient SM (Prescription #'s 7292769 and 7292768).

Both prescriptions were successfully received via electronic transmission from prescriber, Lucia McLendon, MD. They were prepared for Pharmacist review and were subsequently approved. They were also shipped later that afternoon. A few days later, we received a call from the patient's mother, who indicated that her daughter did not request the order they received. Unfortunately, we were not able to provide the mom with any details related to this request and order details, and we upheld all HIPAA provisions and requirements. Moreover, I personally reached out to the prescriber, and validated that both prescriptions were indeed correct and to be dispensed as written. Patient privacy is of utmost importance and is our duty to protect all personal health information related to our clients.

Additionally, I completely understand the concern and involvement of a parent or guardian and can appreciate that they wanted to look into this issue further. I can only imagine how difficult that conversation may have been for this patient and her family. Please know that we take situations like this very seriously and follow strict protocols to ensure the accuracy, validity, and authenticity of prescriptions that we receive. It is our primary focus to provide compassionate care and service to our clients.

Should you have any additional questions or need any additional information, please do not hesitate to contact me.

Best regards,

Jessica Nouhavandi
PIC
Honeybee Health

--
Dr. Jessica Nouhavandi
Co-Founder & President
(she/her)

www.honeybeehealth.com
833-HONEY-RX

honeybee

-------- Forwarded message ---------
From: **Do, Huy@DCA** <Huy.Do@dca.ca.gov>
Date: Thu, Aug 29, 2024 at 4:31 PM
Subject: RE: Written Statement from PIC-Please confirm receipt
To: Jessica Nouhavandi <jessica@honeybeehealth.com>

Received. Thank you and I will contact you if I need any additional information.

Thanks,

Huy Do, Pharm.D., Inspector
California State Board of Pharmacy
(909) 764-7425 | FAX (909) 862-2015 | www.pharmacy.ca.gov

Be Aware and Take Care: Talk to your Pharmacist!

From: Jessica Nouhavandi <jessica@honeybeehealth.com>
Sent: Monday, August 26, 2024 3:06 PM
To: Do, Huy@DCA <Huy.Do@dca.ca.gov>
Subject: Written Statement from PIC-Please confirm receipt

Hello Inspector Do,It was a pleasure meeting you last week during our routine pharmacy inspection. Thank you for providing us with valuable feedback and keeping us informed on the most up to date BPC topics.**Regarding CI 2024 105264, please accept this email correspondence as my written statement regarding the incident related to patient SM (Prescription #'s 7292769 and 7292768).**Both prescriptions were successfully received via electronic transmission from prescriber, Lucia McLendon, MD. They were prepared for Pharmacist review and were subsequently approved. They were also shipped later that afternoon. A few days later, we received a call from the patient's mother, who indicated that her daughter did not request the order they received. Unfortunately, we were not able to provide the mom with any details related to this request and order details, and we upheld all HIPAA provisions and requirements. Moreover, I personally reached out to the prescriber, and validated that both prescriptions were indeed correct and to be dispensed as written. Patient privacy is of utmost importance and is our duty to protect all personal health information related to our clients.Additionally, I completely understand the concern and involvement of a parent or guardian and can appreciate that they wanted to look into this issue further. I can only imagine how difficult that conversation may have been for this patient and her family. Please know that we take situations like this very seriously and follow strict protocols to ensure the accuracy, validity, and authenticity of prescriptions that we receive. It is our primary focus to provide compassionate care and service to our clients.Should you have any additional questions or need any additional information, please do not hesitate to contact me.Best regards,

Jessica Nouhavandi

PIC

Honeybee Health

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INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Outsourcing Facility ___ Wholesaler ___ Hypodermic ___

Date: 8/3/2025 Inspector: Dimpi Patel

Firm: HONEYBEE HEALTH INC DBA HONEYBEE HEALTH Phone: (310) 559-5903

Address: 3515 HELMS AVE City: CULVER CITY Zip: 90232

Ownership: CORPORATION

Permit #: PHY58817 Permit Exp: 9/1/2025 DEA#: [redacted] DEA Exp: 10/31/2026

Date of Self Assessment Form: 6/23/2025 Other Permit #: N/A Date of DEA Inventory: 6/23/2025

Hours M-F: 6am-6pm Hours Saturday: 7am-3:30pm Hours Sunday: 7am-3:30pm

PIC JESSICA S NOUHAVANDI RPH66400 Administrator

RPH Consultant

Staff RPH Name:	License #:
MARC D YOUNG	RPH66291
KENT WONG	RPH73075
PAUL D HAM	RPH80697
JAMES J KIM	RPH50525
MARK JONIFER D MARTINE	RPH82408
TANYA MORIM	RPH71895
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TRANG N SON	RPH58770
KELVIN T TRUONG	RPH85484
YEVGENIYA R AVAGIMOVA	RPH78585
SHOUSHAN S KHAMBEKIAN	RPH88660
CALEB F LYNCH	RPH89006
ANDY R PAK	RPH87274
DORIS S REZVANPOUR	RPH64498

Staff Name:	License #:
ALEJANDRA PEREZ	CLERK
AMANDA R JACKSON	TCH157976
AMBER C COLES	TCH170843
ANA K LOPEZ	TCH176841
ANTHONY GOMEZ	TCH185693
ARACELI A PLATAS	TCH186804
CATRINA TRUJILLO	TCH184380
CHEYENNE R REID	TCH179787
DONALD J BEEZHOLD	TCH22788
ERIC MATSON	CLERK
KRISTINA A VALENZUELA	TCH188265
LEWIS HALL	CLERK
MARIANA A LINARES GUER	TCH202173
MARLEN MERIDA-CRIANO	TCH183388
OLGA A SIMON	TCH103097
PETER G WANG	TCH125618
REX C RANDELL	TCH183938
VIOLETA G MENENDEZ	TCH140877

Inspector Remarks:

Routine Inspection:

- Assisted by PIC Nouhavandi, RPH Young, RPH Wong and RPH Khambekian
- Close door retail pharmacy licensed in 50 states
- Dispenses 2000 prescription per day (60% refills/ 40% new)

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INSPECTION REPORT

- ~ 10 non-HD CNSP per day, 3-4 HD CNSP per week
- ~ 2-3 control medications per day

- Temporary absence of RPH sign: Available, RPH onsite during business hours
- Mail prescriptions: All RXs mailed via USPS, FedEx or UPS, sends temperature trackers with select medications
- Non-sterile compounding: Limited Non-HD and HD
- Wholesalers: Cardinal, Anda, Pharm Source, IPC, Bonita, Top RX, Integral, South Point, and Masters
- Reverse Distributor: Return Solution
- Computer Software: Gardian

Reviewed/Discussed:

- New Notice to Consumer, Interpretive language index, original pharmacy license and current renewal: Posted
- All licensed staff subscribe to BoP email per PIC
- Consultation: none observed during inspection.
- Written notice of consultation: Available and sent with mailed packages
- Pharmacy Self-Assessment: Reviewed 06/23/2025, PIC educated on the availability of 04/2025 draft version
- Compounding Self-Assessment: Reviewed 06/23/2025, PIC educated on the availability of 01/2022 draft version
- Sink with hot and cold running water: Available
- Accessible rest room in store: Available
- Refrigerator temperature: Reviewed
- Name badges: Available
- Staffing ratio: Generally staffed by 5-6 RPH and 6-7 TCH per day
- Patient Center Labeling: Available
- Pharmacy storage waiver: None
- Current inventory: Pharmacy has 2 X Parata and 1 X Parata Max. Regular stock is stored in blue plastic bins (some bins are little dusty). Stock is in date
- Expired drugs are quarantined: Yes
- Security of controlled drugs: Inventory of all controlled drugs kept in locked safe
- Security of Pharmacy: Pharmacy has an outer gate leading to a small parking area and the main building. Pharmacists are the only one with the key to the main building. Pharmacy has alarm system and cameras inside and outside of the pharmacy. Visitors must be let in the building by pharmacy personnel. 3 doors leading to the outside.
- Will call area: Pharmacy has various pods and shipping stations
- RTS status: None, all prescriptions are mailed out and if returned are damaged/disposed.
- Confidential patient information disposal: Third party (Shredder)
- Reverse distribution records: Reviewed last expired return invoice
- QA review for medication errors: Available
- Prescription documents: Majority of prescriptions are electronic, some are telephone (new and transferred)
- CURES is submitted daily: Reviewed submission for 08/03/2025
- PDMP access: All RPHs have PDMP access and checks cures twice, upon dispensing and shipping
- DEA inventory: This pharmacy does not dispense CIIs, reviewed inventory for 06/24/2025
- Quarterly CII/alprazolam 1 & 2mg, tramadol 50mg reconciliation report: Does not dispense these drugs, reviewed inventory for 06/24/2025
- Drug loss: None per PIC
- Acquisition records are maintained separately for control medications RPH signs for it: Reviewed
- CSOS ordering/receiving: Available but have not ordered CII for last 3 years

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INSPECTION REPORT

- Policies and Procedure: Available (License Protection Handbook)
  - Quality Assurance Policy
  - Theft or Impairment Policy
  - Technician Job Duties
  - Language Assistance/Interpreter Service
  - Temporary Absence of Pharmacist

Nonsterile Compounding:

- Nonsterile compounding performed (average 2 batches per day for non-HD, 1 HD batch per week)
- Recall of CNSP: None per PIC
- Nonsterile compounding area:
  - Sink for Hand Hygiene and cleaning: Available
  - Eye wash station: Available
  - Non-HD
    - Dedicated room within the pharmacy
    - PPE available
    - ~~available~~
    - Powder hood
    - PPE available
  - HD
    - Dedicated room within the pharmacy
    - Negative pressure room, Air changes, externally vented
    - Powder hood, externally vented
    - PPE and appropriate cleaning supplies available
  - Spill kit readily available
  - Designated Person: PIC
  - 1 RPH and TCH trained as compounders
- Documents: Reviewed
  - Sample master formulas
  - Sample compounding logs
  - Cleaning logs
  - Staff training records
  - End product testing for non-sterile compounds
  - Temperature and humidity logs
- Prescription labels for compounded products includes "compound" on label
- Policies/procedures for non-sterile compounding: reviewed
  - Annual review of Policies & Procedures by PIC/DP, last reviewed completed on 01/28/2025
  - Dissemination of SOP changes to staff
  - Quality assurance/quality control
  - Processes/techniques for packaging and transporting CNSP's
  - End-Product Testing
  - Beyond Use Dating
  - Training

INSPECTION REPORT

- Complaints
- Hazardous drugs – compounding, handling, garbing, etc.

- Equipment/facilities:
  - Non-sterile HD compounding room certification by Clean Room Services on 05/21/2025– differential pressure, ACPH, hoods
  - Certification of scales by Data Support Co. on 07/22/2025
  - Training:
    - Reviewed for RPH and TCH
      - Hand hygiene
      - Garbing
      - Cleaning and sanitizing
      - Handling and transporting components and CNSP's
      - Measuring and mixing
      - Proper use of equipment and devices selected to compound CNSP's
      - Documentation of the compounding process (MF & CR)
      - Spill management (for all personnel required to clean up a spill)

Discussion:

1. Receiving control drugs
2. Gowning for non-HD compounding must follow SOP
3. Availability of updated Self-Assessments on the Board's website
4. Currently, negative pressure is not documented/reviewed daily
5. Line of demarcation in HD room
6. Security of the pharmacy

Topics to Educate:

1. If a pharmacy is closing in your area, the Board reminds licensees about the provisions of Business and Professions Code (BPC) section 4064 related to emergency refills.
2. The Board's homepage, www.pharmacy.ca.gov, has a **new online pharmacy locator**. It is currently located at the top of the homepage as a banner.
3. As of January 1, 2025, the following licenses are eligible to **renew online** from the Board's website: Pharmacist, Advanced Practice Pharmacist, Pharmacy Technician, Wholesaler Designated Representative, Veterinary Food Animal Drug Retailer Designated Representative, Third Party Logistics Provider Designated Representative, and Reverse Distributor Designated Representative. The Board will no longer mail out paper renewal applications for these license types. In its place, a postcard reminder will be sent approximately six weeks prior to the license expiration date to renew online at www.pharmacy.ca.gov.
4. The Board has implemented a new online portal to **report a drug theft/drug loss of controlled substances** and encourages licensees to use the portal for future reporting: https://www.pharmacy.ca.gov/webapplications/apps/drug_loss/index.shtml.
5. Effective April 1, 2025, pursuant to 16 CCR 1709.1, the proposed PIC is required to complete the Board's **PIC Overview and Responsibility training course** within two years prior to the date of application to serve as a PIC. For this training go to: https://pharmed.thinkific.com/courses/pic.
6. BPC section 4113.1 establishes requirements for a community pharmacy to report medication errors to an entity approved by the Board. In September 2024, the Board approved the Institute for Safe Medication Practices (ISMP), an ECRI company, as the entity to receive and review medication error reports under BPC section 4113.1. Medication errors that occur on or after **September 1, 2025**, must be reported to the California Medication Error Reporting (CAMER) system. To register with ISMP to report medication errors to the CAMER system, go to: https://mederrors.ismp.org/. For technical issues please email: clientservices@ecri.org.
7. *The Script* Newsletter Article: Under federal law, **licensed health professionals employed by a tribal health program** are required to be exempt, if licensed in any state, from licensing requirements of the state in which the tribal health program performs

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

specified services. California law aligns with this requirement, and provides an exemption from California licensure for a health care practitioner, including a physician or pharmacist, licensed in any state who practices as part of a tribal health program. To read the full article in the May 2025 edition of *The Script*, go to: https://www.pharmacy.ca.gov/publications/25_may_script.pdf.

8. Compounding: The Office of Administrative Law has approved the Board's updated compounding regulations. The regulations describe the Board's requirements for nonsterile compounding, sterile compounding, hazardous drugs and radiopharmaceutical preparations. These regulations become **effective October 1, 2025.** During this intervening period, the Board encourages licensees to continue transitioning to the new standards established in USP, and to take steps to establish compliance with the Board's updated regulations.

9. As a reminder, **BPC section 4113**(d) requires the PIC or pharmacist on duty to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Store management must take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or pharmacist on duty must ensure the Board is timely notified. Such conditions include, but are not limited to: workplace safety and health hazards, sustained temperatures that could impact ambient temperature drug stability according to the manufacturer data on acceptable drug storage conditions, and vermin infestation that poses a risk to the safety or efficacy of medicine.

DISCLAIMER:

Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection may result in further communication after this report.

To complete this inspection, please provide the following to Inspector Dimpi Patel via email (Dimpi.Patel@dca.ca.gov) **no later than 08/18/2025:**

1. Completed training for RPH for HD Compounding

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) [signature]

Pharmacist (print) Jessica Nouhavandi

Inspector (sign) [signature] 7/14/25

Inspector (print) Dimpi Patel

Owner(sign) [signature]

Owner(print) Jessica Nouhavandi

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State
Board of Pharmacy

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
www.pharmacy.ca.gov

DIMPI PATEL, Pharm.D.
Inspector

(714) 649-6163
(916) 702-6017 Fax
dimpi.patel@dca.ca.gov

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58817

NAME: HONEYBEE HEALTH INC DBA HONEYBEE HEALTH

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

3515 HELMS AVE
CULVER CITY CA 90232
LOS ANGELES COUNTY

ISSUANCE DATE

SEPTEMBER 2, 2022

EXPIRATION DATE

SEPTEMBER 1, 2026

CURRENT DATE / TIME

JANUARY 6, 2026
11:30:25 AM

LICENSE RELATIONSHIPS

NAME: NOUHAVANDI, JESSICA SAHAR

ADDRESS NOT DISCLOSED

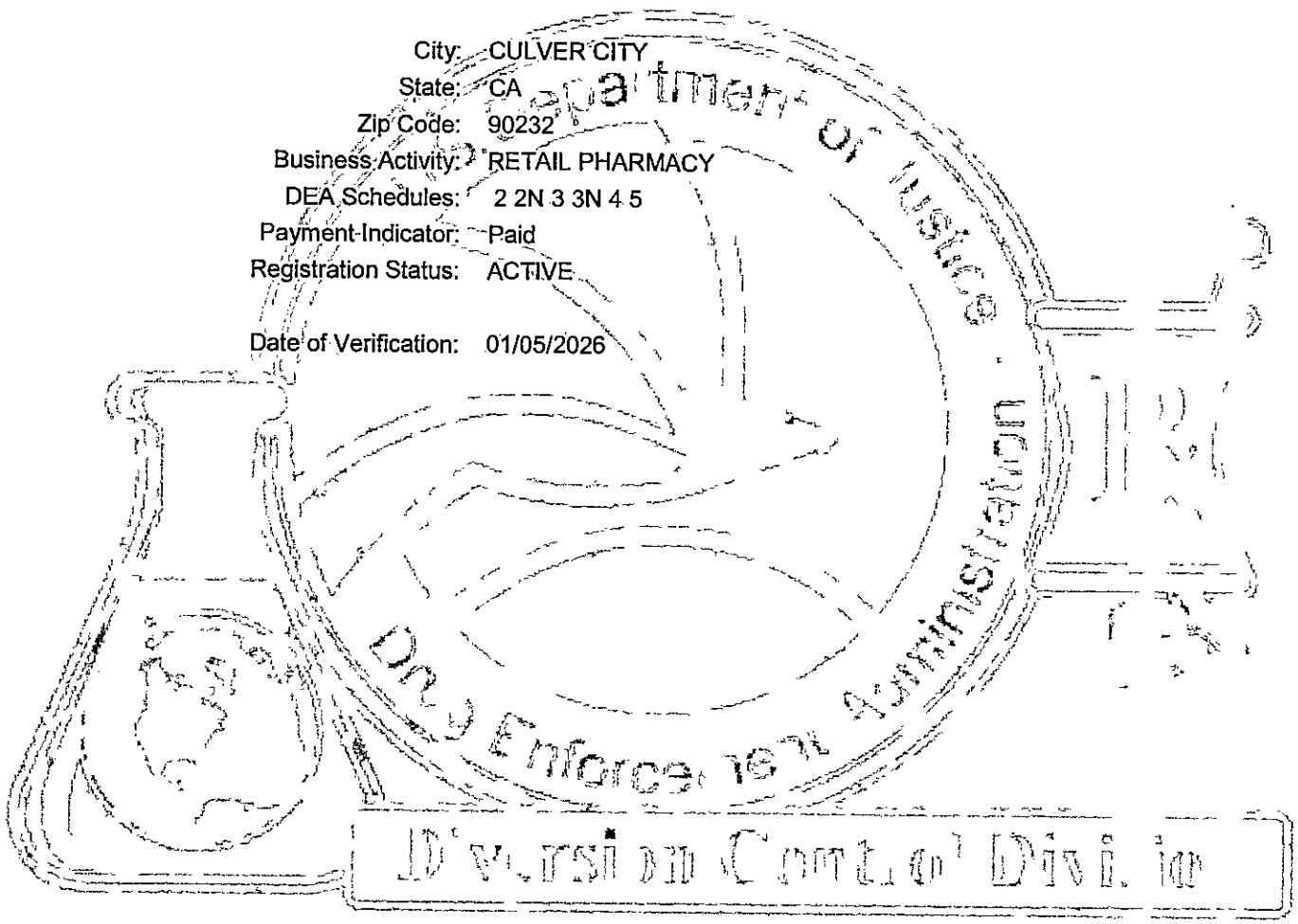
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 66400 **PRIMARY STATUS:** CLEAR

Registrant Verification For

HONEYBEE HEALTH, INC.

DEA Number:	FH7188875
Expiration Date:	10/31/2026
Additional Company Info:	DBA: HONEYBEE HEALTH
Registered Address:	3515 HELMS AVE
City:	CULVER CITY
State:	CA
Zip Code:	90232
Business Activity:	RETAIL PHARMACY
DEA Schedules:	2 2N 3 3N 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	01/05/2026



This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

Drug Enforcement Administration • Diversion Control Division • 75 Morrissette Dr, Springfield, VA 22152

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Honeybee Health, Inc. d/b/a Honeybee Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 03867

Physical Address: 3515 Helms Avenue

City: Culver City State: CA Zip: 90232

Mailing Address (if different from physical address): Same as Above

City: State: Zip:

Telephone: 833-466-3979 Website: www.honeybeehealth.com

Licensing Company Email: jessica@honeybeehealth.com

Section 2: Personal Information

First: Peter Middle: Gang Last: Wang

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Minnesota		2000-2005	
Address	City	State	Zip
100 Church Street	Minneapolis	MN	55455
Diploma/Degree obtained, if any			
Bachelor of Arts in Communication Studies			

School Name		From - To (MM/YY – MM/YY)	
Roseville Area High School		1996-2000	
Address	City	State	Zip
1240 County Road B2 W	Roseville	MN	55113
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
NA			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Honeybee Health Inc.			09/2017 - Present
Business Address	**City**	**State**	**Zip**
3515 Helms	Culver City	CA	90232
Phone	**Title**		
833-466-3979	Co-Founder and CEO		

Description of Duties

Executive role & drive business growth overseeing company expansion.

Business Name			From - To (MM/YY – MM/YY)
MCP Pharmacy			2011-2017
Business Address	**City**	**State**	**Zip**
865 Patriot Dr #103	Moorpark	CA	93021
Phone	**Title**		
	Co-Founder and CEO		

Description of Duties

Founded and scaled pharmacy business from inception

Business Name			From - To (MM/YY – MM/YY)
NA			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
NA			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/23/2022		AZ	Phoenix	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
#22-0012		Arizona Board of Pharmacy		
Reason/Charge				
Failure to report the Idaho disciplinary action				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Arizona – case #22-0012. On June 23, 2022, Honeybee received an Order for Non-Disciplinary Civil Penalty for Honeybee's failure to report the Idaho Stipulation and Consent Order on the pharmacy's Arizona renewal application. Honeybee paid a penalty in the amount of $250.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1/19/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/17/2022		HI	Honolulu	Honolulu
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
#PHA-2021-49-L		Hawaii Board of Pharmacy		
Reason/Charge				
Previous disciplinary action imposed by the Idaho Board of Pharmacy				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Hawaii (reciprocal) – case #PHA-2021-49-L. On February 17, 2022, Honeybee received a fully executed Settlement Agreement. Honeybee agreed to pay a penalty of $500 for earlier discipline imposed by the Idaho State Board of Pharmacy.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.



Original Signature (electronic, copies or stamps not accepted)

1/19/2026

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/26/2021		ID	Boise	Ada
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
#BOP - 21- 076		Idaho Board of Pharmacy		
Reason/Charge				
Improper registration of Idaho pharmacist in charge				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Idaho – case #BOP-21-076. On August 26, 2021, Honeybee received a fully executed Stipulation and Consent Order from the State of Idaho. Honeybee agreed to discipline for not maintaining a properly registered Idaho pharmacist-in-charge. Honeybee paid a penalty in the amount of $4,000.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1/19/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Peter Wang

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/19/2026

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Peter Gang Wang, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/19/2026

Date

State of California County of Los Angeles

Subscribed and Sworn to before me this 19th day of January 2026

Notary Public Signature Adam S. Goldman

ADAM S. GOLDMAN
Notary Public - California
Los Angeles County
Commission # 2476626
My Comm. Expires Jan 13, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Honeybee Health, Inc. d/b/a Honeybee Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 03867

Physical Address: 3515 Helms Avenue

City: Culver City State: CA Zip: 90232

Mailing Address (if different from physical address): Same as Above

City: State: Zip:

Telephone: 833-466-3979 Website: www.honeybeehealth.com

Licensing Company Email: jessica@honeybeehealth.com

Section 2: Personal Information

First: Jessica Middle: Sahar Last: Nouavandi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western University of Health Sciences		2007 -- 2011	
Address	**City**	**State**	**Zip**
309 E 2nd St	Pomona	CA	91766
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
America Jewish University		2002-2006	
Address	**City**	**State**	**Zip**
15600 Mulholland Dr	Los Angeles	CA	90077
Diploma/Degree obtained, if any			
Bachelor of Science in Bioethics			

School Name		From - To (MM/YY – MM/YY)	
University High School		1998-2002	
Address	**City**	**State**	**Zip**
11800 Texas Ave	Los Angeles	CA	90025
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
NA			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Honeybee Health, Inc. d/b/a Honeybee Health			09/2017 - Present
Business Address	**City**	**State**	**Zip**
3515 Helms Avenue	Culver City	CA	90232
Phone	**Title**		
833-466-3979	Co-Founder, COO, and Pharmacist in Charge		
Description of Duties			
Responsible for all pharmacy operations.			

Business Name			From - To (MM/YY – MM/YY)
NA			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/23/2022		AZ	Phoenix	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
#22-0012		Arizona Board of Pharmacy		
Reason/Charge				
Failure to report the Idaho disciplinary action				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Arizona – case #22-0012. On June 23, 2022, Honeybee received an Order for Non-Disciplinary Civil Penalty for Honeybee's failure to report the Idaho Stipulation and Consent Order on the pharmacy's Arizona renewal application. Honeybee paid a penalty in the amount of $250.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1-19-26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/17/2022		HI	Honolulu	Honolulu
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
#PHA-2021-49-L		Hawaii Board of Pharmacy		
Reason/Charge				
Previous disciplinary action imposed by the Idaho Board of Pharmacy				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Hawaii (reciprocal) – case #PHA-2021-49-L. On February 17, 2022, Honeybee received a fully executed Settlement Agreement. Honeybee agreed to pay a penalty of $500 for earlier discipline imposed by the Idaho State Board of Pharmacy.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1-19-26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/26/2021		ID	Boise	Ada
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
#BOP - 21- 076		Idaho Board of Pharmacy		
Reason/Charge				
Improper registration of Idaho pharmacist in charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				
Honeybee Health Inc., Pharmacy				

Provide explanation below:

Honeybee Health, Inc. has the following past actions. Please note, Honeybee has taken robust corrective measures to ensure full compliance and remains committed to following all state licensing laws, as well as any federal and state regulations.

Idaho – case #BOP-21-076. On August 26, 2021, Honeybee received a fully executed Stipulation and Consent Order from the State of Idaho. Honeybee agreed to discipline for not maintaining a properly registered Idaho pharmacist-in-charge. Honeybee paid a penalty in the amount of $4,000.

Please note this was previously reported to the Nevada Board of Pharmacy.

Please see exhibit A.

Original Signature (electronic, copies or stamps not accepted)

1-19-26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Nouhavandi

Print Name (First, Last)

jnouhavandi — 1-19-26

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Jessica Nouhavandi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

jnouhavandi — 1-19-26

Original Signature — **Date**

State of California County of Los Angeles

Subscribed and Sworn to before me this 19th day of January 2026.

Notary Public Signature Adam S Goldman

ADAM S. GOLDMAN
Notary Public - California
Los Angeles County
Commission # 2476626
My Comm. Expires Jan 13, 2028

(Seal)

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 03505		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Factor One Source Pharmacy, LLC dba InfuCare Rx of MD

Physical Address: 217 Glenn Street 3rd Floor, Suite 300

City: Cumberland State: MD Zip: 21502

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 844-773-6779 Toll Free # (NAC 639.708, NRS 639.23286): 844-773-6779

Fax: 844-533-1131 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christina Nutter

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22620

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christina Nutter	NV Pharmacist Registration #: 22620
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MD

Parent Company (if any): InfuCare Rx, Inc.

Corporation/Organization Name: Factor One Source Pharmacy, LLC dba InfuCare Rx of MD

Mailing Address: 217 Glenn Street, Suite 300

City: Cumberland State: MD Zip: 21502

Telephone: 877-828-3940 Email: Licensing@infucarerx.com

Contact Person Name: Jessica Seefried

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Corporate Secretary and General Counsel (title) for Factor One Source Pharmacy, LLC dba InfuCare Rx of MD (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Tiffany Scheppers

Print Name of Authorized Person

Original Signature of Authorized Person (copies or stamps not accepted)

11/19/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Christina Nutter hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for Factor One Source Pharmacy, LLC dba InfuCare Rx of MD (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of Nov, 20 25

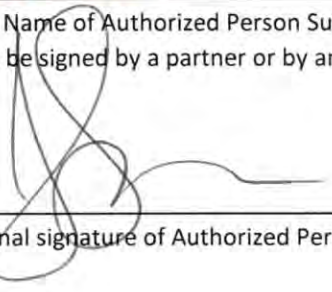
Notary Public

KIMBERLY T CALCUTTA
Notary Public - State of Maryland
Allegany County
My Commission Expires Mar 12, 2028

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

11/19/2025

Date

Board Use Only	Date Received: 12/8/25	Amount: $500 EK 10000024110

Pre- and Post- Sale for Factor One Source Pharmacy, LLC

Pre-Close Structure



Post-Close Structure



Corporate Officers			
Name	**Title**	**Address**	**Phone**
Dhara Patel	President, Director, and Treasurer	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940
Tiffany Scheppers	Secretary and General Counsel	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940

Factor One Source Pharmacy, LLC DBA InfuCare Rx of MD			
217 Glenn Street 3rd Floor, Suite 300, Cumberland, MD 21502			
List of Shareholders			
Name	**Address**	**Phone**	**Percent Ownership**
InfuCare Rx, Inc.	695 US Hwy 46, Ste 100, Fairfield, NJ 07004	877-828-3940	100%

STATE OF MARYLAND
Department of Assessments and Taxation

I, BOB YEAGER OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO LIMITED LIABILITY COMPANIES , OR THE RIGHTS OF LIMITED LIABILITY COMPANIES TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT FACTOR ONE SOURCE PHARMACY LLC (W15747702) , REGISTERED MARCH 19, 2014, IS A LIMITED LIABILITY COMPANY EXISTING UNDER AND BY VIRTUE OF THE LAWS OF THE STATE OF MARYLAND, AND THAT THE LIMITED LIABILITY COMPANY IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING TO TRANSACT BUSINESS.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS OCTOBER 17, 2025.

Bob Yeager
Director

700 East Pratt Street, 2nd Flr, Ste 2700, Baltimore, Maryland 21202
Telephone Baltimore Metro (410) 767-1344 / Outside Baltimore Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice

Online Certificate Authentication Code: 4K9QEainoUmoV5K9CRt7vw
To verify the Authentication Code, visit http://dat.maryland.gov/verify

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Factor One Source Pharmacy, LLC dba InfuCare Rx of MD

Pharmacy/Wholesaler License # (if applicable): PH03505

Physical Address: 217 Glenn Street, Suite 300

City: Cumberland State: MD Zip: 21502

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 844-773-6779 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Christina Middle: Marie Last: Nutter

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bernard J Dunn School of Pharmacy at Shenandoah University			08/03-06/07	
Address		City	State	Zip
1775 N. Sector Ct		Winchester	VA	22601
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
North Harris Community College			08/97-12/00	
Address		City	State	Zip
2700 W. Thorne Dr		Houston	TX	77073
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Montgomery Community College			08/01-06/03	
Address		City	State	Zip
51 Mannakee Street		Rockville	MD	20850
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Montgomery Community College			08/01-06/03	
Address		City	State	Zip
20200 Observation Dr #4067		Germantown	MD	20876
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY	
Damascus High School			08/93-06/97	
Address		City	State	Zip
25921 Ridge Rd		Damascus	MD	20872
Diploma/Degree obtained, if any				
High School Diploma				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
07/20- Present	[redacted]			
From - To (MM/YY – MM/YY)				
05/12-07/20				
From - To (MM/YY – MM/YY)				
05/11-05/12				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Factor One Source Pharmacy, LLC dba InfuCare Rx of MD			11/20 - Present	
Business Address		**City**	**State**	**Zip**
217 Glenn Street, Suite 300		Cumberland	MD	21502
Phone	**Title**		**Number of Employed Hours**	
844-773-6779	Pharmacist in Charge / Staff pharmacist		14480	
Description of Duties				
Supervise all aspects of the Maryland Branch (Pharmacist in Charge). Head the operations of the Hemophilia Center of Excellence at the Maryland branch. Clinical pharmacist for hemophilia, IVIG/SCIG, and Specialty injectables.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Christina Marie Nutter, **certify that as the designated representative for**

Factor One Source Pharmacy, LLC dba InfuCare Rx of MD,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CMN I am at least 21 years of age;
3. CMN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CMN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CMN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CMN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CMN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christina Nutter

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/18/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christina Nutter

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/18/25

Date

Please have this section completed in the presence of a Notary Public.

State of MARYLAND, ss. County of Allegany

I, Christina Nutter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/18/25

Date

Subscribed and Sworn to before me this 18 day of NOV.

Kimberly T Calcutta

Notary Public Signature

KIMBERLY T CALCUTTA
Notary Public - State of Maryland
Allegany County
My Commission Expires Mar 12, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Factor One Source Pharmacy, LLC dba InfuCare Rx of MD

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03505

Physical Address: 217 Glenn Street 3rd Floor, Suite 300

City: Cumberland State: MD Zip: 21502

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 844-773-6779 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Dhara Middle: Devendra Last: Patel

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: FL Zip: 32259

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Armstrong Atlantic State University		Unknown	
Address	**City**	**State**	**Zip**
11935 Abercorn St.	Savannah	GA	31419
Diploma/Degree obtained, if any			
Bachelors Degree in Liberal Arts			

School Name		From - To (MM/YY – MM/YY)	
Richmond Hill High School		Unknown	
Address	**City**	**State**	**Zip**
Unknown			
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
Unknown-Present				
From - To (MM/YY – MM/YY)				
Unknown-Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
InfuCare Rx, Inc.			2015 - Present	
Business Address	**City**	**State**	**Zip**	
695 US Hwy 46, STE 100	Fairfield	NJ	07004	
Phone	**Title**			
877-828-3940	President			
Description of Duties				
President of InfuCare Rx, Inc.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Passaic

I, Dhara Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/2/2025

Date

Subscribed and Sworn to before me this 2nd day of December, 2025.

Notary Public Signature

DANIEL ALBARRAN
Notary Public, State of New Jersey
My Commission Expires Dec 15, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Factor One Source Pharmacy, LLC dba InfuCare Rx of MD

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03505

Physical Address: 217 Glenn Street, Suite 300

City: Cumberland State: MD Zip: 21502

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 844-773-6779 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Tiffany Middle: Samantha Last: Scheppers

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri St Louis		Unknown	
Address	**City**	**State**	**Zip**
1 University Blvd.	St. Louis	MO	63121-4400
Diploma/Degree obtained, if any			
MBA not completed			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University School of Law		8/1996-5/1999	
Address	**City**	**State**	**Zip**
100 N Tucker Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University		8/1993-5/1999	
Address	**City**	**State**	**Zip**
1 N Grand Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Nursing			

School Name		From - To (MM/YY – MM/YY)	
Cornelia Connelly School of the Holy Child Jesus		1984-1988	
Address	**City**	**State**	**Zip**
2323 W Broadway	Anaheim	CA	92804
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
8/2015-present				
From - To (MM/YY – MM/YY)				
3/2013-8/2015				
From - To (MM/YY – MM/YY)				
1/2000-3/2013				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Infucare Rx Inc.			03/2021 - Present
Business Address	**City**	**State**	**Zip**
695 US Hwy 46, STE 100	Fairfield	NJ	07004
Phone	**Title**		
877-828-3940	General Counsel and Corporate Secretary		

Description of Duties

Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
973-564-8004	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secretary		

Description of Duties

Oversee all corporate, regulatory, employment, litigation, and compliance legal matters; Current Officer acting as Corporate Secretary; Advised executive leadership and Board of Directors on complex regulatory compliance matters.

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			03/2019 - 07/2019
Business Address	**City**	**State**	**Zip**
N/A	Charlotte	NC	N/A
Phone	**Title**		
314-808-3974	Outside General Counsel		

Description of Duties

Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, re: health care, pharma, biotech and CRO/CSO companies on legal and regulatory.

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
919-876-9300	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		

Description of Duties

Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Mecklenburg

I, Tiffany Scheppers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2025

Date

Subscribed and Sworn to before me this 19 day of November 2025.

Notary Public Signature

NIMESH R. PATEL NOTARY PUBLIC MECKLENBURG COUNTY, N.C.

My Commission Expires
Nov 7, 2029

(Seal)

MARYLAND
Department of Health
Wes Moore, Governor - Aruna Miller, Lt. Governor - Laura Herrera Scott, M.D., M.P.H, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Kristopher Rusinko, PharmD, Board President, Deena Speights-Napata, Executive Director

COMMUNITY PHARMACY INSPECTION FORM

Maryland Pharmacy Permit Number	:	PW0521
Corporate Pharmacy Name	:	FACTOR ONE SOURCE PHARMACY LLC dba INFUCARE RX OF MD
Pharmacy Name-Doing Business as (d/b/a) or Trade Name	:	
Street Address	:	217 Glenn Street, Cumberland, MD, 21502
Business Telephone Number	:	844-773-6779
Business Fax Number	:	301-876-4395
Inspection Date	:	04/04/2025
Arrival Time	:	10:11
Departure Time	:	12:23:27
Type of Inspection	:	◉ Annual
Previous Date	:	10/19/2023
Name of Inspector	:	Monica Kunkle

1. GENERAL INFORMATION

◉ Yes ○ No The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment.

Pharmacy Hours			
Monday: 9:00am-5:00pm	Tuesday: 9:00am-5:00pm	Wednesday: 9:00am-5:00pm	Thursday: 9:00am-5:00pm
Friday: 9:00am-5:00pm	Saturday: Closed	Sunday: Closed	

◉ Yes ○ No All permits, licenses, and registrations are posted conspicuously. HO § 12-311, HO § 12-408(b) and HO § 12-6B-08

Maryland Pharmacy Permit Number	PW0521	Expiration Date	05/31/2026
CDS Registration Number	499024	Expiration Date	11/30/2027
DEA Registration Number	FF8097239	Expiration Date	09/30/2027

○ Yes ◉ No The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

○ Yes ◉ No The pharmacy provides services to Comprehensive Care facilities or assisted living facilities. (If yes, complete Comprehensive Inspection Form) COMAR 10.34.23

○ Yes ◉ No The pharmacy fills original prescriptions received via the internet.

◉ Yes ○ No The pharmacy fills original prescriptions via e-prescribing.

○ Yes ◉ No The pharmacist fills mail order prescriptions.

If yes to any of the above, how does the pharmacist verify that a relationship exists between the patient and the prescriber? 21 C.F.R. § 1306.04, HG § 21-220; COMAR 10.19.03.02 and .07

Comments: Pharmacy receives electronic prescriptions through a secure site, would call Prescriber with any questions or concerns. Pharmacy does mail out prescriptions to Patients through Fedex. Pharmacy is licensed in other States. (List Attached)

2. PERSONNEL

Name of Pharmacist Manager who is charged with ensuring compliance with all applicable laws:

23949 23949: Christina Marie Nutter

Pharmacist Employee	License #	Status	Exp. Date	Vaccine Certification #	Status	Exp. Date	
THOMAS C SHERN	12286	Active	07/31/2026	12286	Inactive	07/31/2024	
Christina Marie Nutter	23949	Active	01/31/2026	23949	Inactive	01/31/2022	
JONATHAN B MILLER	18127	Active	03/31/2026	18127	Inactive	03/31/2018	

Registered Technicians	Registration #	Status	Exp. Date	
AMANDA M. COMBS	T12084	Active	08/31/2026	
ALEXA L SPRIGGS	T09058	Active	12/31/2026	
Emily L Gulick	T19073	Active	05/31/2026	
April J Schurg	T03396	Active	07/31/2026	
Heather Nicole Wolfkill	T18025	Active	12/31/2025	
Alec Ryan Chapman	T30168	Active	07/31/2025	

Unlicensed Personnel (non-registered)	Title	Duties	
N/A	N/A		

No Vaccinating Pharmacist were on duty at time of inspection. Pharmacy does not provide vaccination services, no vaccines were in stock at time of inspection.

Comments:

3. PERSONNEL TRAINING

Yes No N/A There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03 and 10.34.21.05

Yes No N/A All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1)

All personnel have received training in: (check all that apply) COMAR 10.34.21.03B(3) and (4)

Yes No N/A Maintaining records

Yes No N/A Patient confidentiality

Yes No N/A Sanitation, hygiene, infection control

Yes No N/A Biohazard precautions

Yes No N/A Patient safety and medication errors COMAR 10.34.26.03

Comments:

Policies and Procedures are located in ADP App and Sharepoint.
Training is completed through Healthicity. Reviewed.

Yes No The pharmacy wholesale distributes to another pharmacy (COMAR 10.34.37)

Yes No The pharmacy wholesale distributes to a wholesale distributor (COMAR 10.34.37)

Yes No N/A The wholesale distribution business exceeds 5% of the pharmacy annual sales (COMAR 10.34.37)

Comments:

No wholesale distribution per Pharmacist Thomas Shern.

4. SECURITY COMAR 10.34.05

Yes No The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

Comments:

Pharmacy has locked doors to prevent entry when Pharmacy is closed and remainder of office building is open.

Yes No The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

Yes No The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A (3)

Comments:

Observed cameras, motion detectors, door sensors, and alarm panel during inspection.

5. PHYSICAL REQUIREMENTS AND EQUIPMENT

◉ Yes ○ No	Pharmacy area is clean and orderly. HO § 12-403(b) (11) (ii)2.
○ Yes ◉ No	The pharmacy provides a compounding service (non-sterile procedures).
◉ Yes ○ No	If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02
◉ Yes ○ No	The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
◉ Yes ○ No	The pharmacy has hot and cold running water.
◉ Yes ○ No	The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
◉ Yes ○ No	The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP. COMAR 10.34.07.01B
Temperature	41F, 37F, 40F, 39F, 38F, 40F
◉ Yes ○ No	The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)
Temperature	74F
◉ Yes ○ No ○ N/A	If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.
Temperature	-11F, -10.
◉ Yes ○ No	The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10)
◉ Yes ○ No	The pharmacy has online resources. HO § 12-403(b)(15)

Comments:

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Pharmacy did not have any vaccines stored in fridge at time of inspection.
Pharmacy did not have any medication stored in freezer at time of inspection.
Pharmacy does not provide any sterile or non-sterile compounding.
```

6. PRESCRIPTION LABELING, FILES AND STORAGE

◉ Yes ○ No Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)

The following label requirements are met if a drug is dispensed pursuant to a prescription: HO § 12-505

◉ Yes ○ No The name and address of the pharmacy; HG § 21-221(a)(1)

◉ Yes ○ No The serial number of the prescription; HG § 21-221(a)(2)

◉ Yes ○ No The date the prescription was filled; HO § 12-505(b)(1) and HG §21-221(a)(3)

◉ Yes ○ No The name of the prescriber; HG § 21-221(a)(4)

◉ Yes ○ No The name of the patient; HG § 21-221(a)(5)(i)

◉ Yes ○ No The name and strength of the drug or devices; HO § 12-505(c)

◉ Yes ○ No The directions for use; HO § 12-505(b)(2)(ii) and HG §21-221(a)(5)(ii)

◉ Yes ○ No The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii)

◉ Yes ○ No The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2)

◉ Yes ○ No The expiration date is indicated; HO § 12-505(b)(2)

◉ Yes ○ No The pharmacist and data-entry technician initials are on prescriptions. COMAR 10.34.08.01

◉ Yes ○ No Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503

Comments:

```
See attached label.
Pharmacist and Technician initials are present on label.
Pharmacy has not ordered, dispensed or stocked CII-CV medications, attached non-control label.
```

7. QUALITY ASSURANCE - PATIENT SAFETY / MEDICATION ERRORS

◉ Yes ○ No There are written policies that inform patients of the procedure to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care povider. COMAR 10.34.26.02

◉ Yes ○ No The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the roles and responsibilities of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

◉ Yes ○ No There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

Comments:
Medication Error Reporting for the Patient is provided in "Patient Admission Package" when medication is dispensed.
Reviewed two continuous years training in preventing medication errors for one Pharmacist and one Technician.
Q/A is reported internally to Quality Management Committee.

8. CONFIDENTIALITY

- (●) Yes ( ) No Confidentiality is maintained in the creation, storage, access disposal and disclosure of patient records. HO § 12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations
- (●) Yes ( ) No Any identifiable information contained in a patient's record is not disclosed unless authorized by the patient, or an order of the court, or as authorized pursuant to HG §4-301 through §4-307. COMAR 10.34.10.03B

Comments:
Pharmacy uses Iron Mountain for disposal of HIPAA information.
No visible PHI was observed during inspection.

9. INVENTORY CONTROL PROCEDURES

- (●) Yes ( ) No ( ) N/A The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR10.34.24.03
- (●) Yes ( ) No ( ) N/A The pharmacy has a procedure in place for removal of all expired drugs (both prescription and OTC). COMAR 10.34.12.01
- ( ) Yes ( ) No (●) N/A The pharmacy maintains records of wholesale distribution to other pharmacies separately from its other records. COMAR 10.34.37.03
- ( ) Yes ( ) No (●) N/A The pharmacy maintains records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to other pharmacies. COMAR 10.34.37.03

Comments:
Policies and Procedures are located in ADP App and in Sharepoint.
No wholesale distribution per Pharmacist Thomas Shern.

10. CONTROLLED SUBSTANCES

N/A
(No control medications are ordered, stocked or dispensed by pharmacy)

Power of Attorney: N/A

- (●) Yes ( ) No The pharmacy has a record of the most recent required biennial inventory of Schedule II - V controlled substances. COMAR 10.19.03.05B
  Inventory Date: 02/28/2025
  Biennial Inventory completed at
  (●) Opening ( ) Closing
- (●) Yes ( ) No The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
- ( ) Yes (●) No Records are kept of all receipts of controlled substances entered into the pharmacy inventory (including DEA Form 222 or CSOS orders). COMAR 10.19.03.05
- ( ) Yes (●) No There are written policies and records for return of CII, CIII-V.
- (●) Yes ( ) No Hard copy or electronic prescription files are maintained chronologically for 5 years.
- ( ) Yes (●) No Schedule II controlled substances are dispersed throughout the stock of non-controlled substances or stored in such a manner as to obstruct theft or diversion. COMAR 10.19.03.12B (2)
- ( ) Yes (●) No All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)
- ( ) Yes (●) No The permit holder or pharmacist designee(s) has written policies and procedures for investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)

Comments:
Pharmacy has not ordered, dispensed or stocked CII-CV medications.

11. AUTOMATED MEDICATION SYSTEMS ( ) Yes (●) No (if No, go to #12)

( ) Yes ( ) No (●) N/A The facility uses an automated device(s) as defined in COMAR 10.34.28.02.

Policies and procedures exist for (check all that apply): COMAR 10.34.28.04A

( ) Yes ( ) No (●) N/A Operation of the system

Yes No N/A Training of personnel using the system

Yes No N/A Operations during system downtime

Yes No N/A Control of access to the device

Yes No N/A Accounting for medication added and removed from the system.

Yes No N/A Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safe guards. COMAR 10.34.28.06

No automated medication systems.

Adequate records are maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11

Yes No N/A Maintenance records.

Yes No N/A System failure reports.

Yes No N/A Accuracy audits.

Yes No N/A Quality Assurance Reports.

Yes No N/A Reports on system access and changes in access.

Yes No N/A Training records.

Yes No N/A Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, dosage forms, or drug entities, and minimize the potential for misidentification of medications, dosages, and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B

Yes No N/A The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

Comments:

No automated medication systems.

12. OUTSOURCING ○ Yes ◉ No (if No, go to #13)

Yes No N/A The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02

Yes No N/A The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02

Yes No N/A The facility serves as a secondary pharmacy. COMAR 10.34.04.02

Yes No N/A The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.

If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number: COMAR 10.34.04.06E

Comments:

No outsourcing.

Yes No N/A The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)

If the pharmacy outsources a prescription order:

Yes No N/A The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D

Yes No N/A Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06

Yes No N/A Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05

12. OUTSOURCING Yes No (if No, go to #13)

The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner: COMAR 10.34.04.06 (Check all that apply)

○ Yes ○ No ◉ N/A	That the prescription order was prepared by a secondary pharmacy.
○ Yes ○ No ◉ N/A	The name of the secondary pharmacy.
○ Yes ○ No ◉ N/A	The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
○ Yes ○ No ◉ N/A	The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
○ Yes ○ No ◉ N/A	The date on which the prescription order was transmitted to the secondary pharmacy.
○ Yes ○ No ◉ N/A	The date on which the medication was sent to the primary pharmacy.
○ Yes ○ No ◉ N/A	The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F
○ Yes ○ No ◉ N/A	The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes: COMAR 10.34.04.07 (Check all that apply)

○ Yes ○ No ◉ N/A	That the prescription order was transmitted from another pharmacy.
○ Yes ○ No ◉ N/A	The name and information identifying the specific location of the primary pharmacy.
○ Yes ○ No ◉ N/A	The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
○ Yes ○ No ◉ N/A	The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
○ Yes ○ No ◉ N/A	The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
○ Yes ○ No ◉ N/A	The date on which the prescription order was received at the secondary pharmacy.
○ Yes ○ No ◉ N/A	The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

13. Recommended Best Practices

○ Yes ◉ No	A perpetual inventory is maintained for Schedule II controlled substances.
◉ Yes ○ No	There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
◉ Yes ○ No	The pharmacy has written policies and procedures for the safe handling of drug recalls. See www.recalls.gov
◉ Yes ○ No	The pharmacy maintains records of all recalls. See www.recalls.gov

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: FACTOR ONE SOURCE PHARMACY LLC dba INFUCARE RX OF MD
Permit#: PW0521
Date: 04/04/2025

Rx#: 235962
Date Filled: 04/03/2025

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY	
N/A	N/A			Clear
N/A	N/A			Clear

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY	
N/A	N/A			Clear
N/A	N/A			Clear

Pharmacy has not ordered, dispensed or stocked control medication (CII-CV).

Comments:

SCHEDULE II AUDIT

	Drug:	N/A
	NDC Number:	N/A
	Date of last Inspection/Biennial:	10/19/2023
Amount at last inspection/biennial	0.00	(A)
Purchased since inspection/biennial	0.00	(B)
Total inventory	0	(C) = A + B
Quantity Dispensed	0.00	(D)
Expected Inventory	0	(E) = C - D
Quantity on Hand	0.00	(F)
Discrepancy	0	(G) = (F-E)excess or (E-F) shortage

INVOICE REVIEW

Pharmacy has not ordered, dispensed or stocked CII-CV medications

CII:

Pharmacy has not ordered, dispensed or stocked CII-CV medications

CIII - CV:

PRESCRIPTION REVIEW

CII#: 0

Date: 0

Pharmacy has not ordered, dispensed or stocked CII-CV medications

Comments:

CIII - CV#: 0

Date: 0

Pharmacy has not ordered, dispensed or stocked CII-CV medications

Comments:

Choose File No file chosen

SPRXPO please contact The Sourcing Group at 800-849-1795

FEED THIS DIRECTION

InfuCare Rx of MD
217 Glenn St., Suite 300, Cumberland, MD 21502-6779

Rx # 235962 04/03/2025

[redacted] Raceland, LA 70394

Amjevita Pen 2 x 40mg/0.8mL
Inject 40mg/0.8mL (1 Pen) subcutaneously every 2 weeks

Mfg: AMGEN USA
Qty: 2 Refills: 11 Discard After: 03/20/2026
MDB, Boudreaux, RPh: AC/TS

Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

235962$%1

[redacted]

Rx # 235962

colorless,

For refills, tear this tag off and bring it in

Pharmacist Signature for Controlled Dangerous Substances Audit: Thomas Shern

INSPECTOR'S COMMENTS:

Reviewed the entire inspection report with Pharmacist Thomas Shern.

URAC accreditation expires May 1, 2025.
ACHC accreditation expires December, 1, 2026.

This is a specialty pharmacy specializing in mostly Factor 7 and Factor 8 and IVIG.
Pharmacy also dispenses Specialty Self administered Injectables. Contract nursing is provided if self-administration is not an option. Pharmacy has limited stock of other medications.

Prescriptions are packaged using ice packs, have temperature monitoring stickers and shipped via FedEx as overnight priority. Orders are mailed directly to patients. Pharmacy is licensed in other states (See attached listed).

No control (CII-V) medications are ordered, stocked or dispensed.

No expired medication was found during spot check of Pharmacy area.
Pharmacy does not stock OTC products outside the Pharmacy area.

Pharmacy is clean, well organized and records were easily accessible.

These matters may be forwarded to the Board for further review.

Inspector Signature: Monica Kunkle

Pharmacist Name (Print): 12286 12286: THOMAS C SHERN Date: 04/04/2025

Signature: Thomas Shern

Received a copy of this inspection report: Thomas Shern

Supporting Documents.
PW0521_04042025_7279_IfuCare Rx of MD_Biennial.pdf
PW0521_04042025_7279_IfuCare Rx of MD_State Licenses.pdf

410-764-4755 - Fax 410-384-4137 - Toll Free 800-542-4964
MDH 1-877-463-3464 - Maryland Relay Service 1-800-735-2258
Web site: https://health.maryland.gov/pharmacy/Pages/index.aspx

PHARMACY WAIVER REGISTRATION

168640

STATE OF MARYLAND
DEPARTMENT OF HEALTH

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Factor One Source Pharmacy LLC Dba Infucare Rx Of Md
217 Glenn Street
Suite #300
Cumberland MD 21502

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Factor One Source Pharmacy Llc Dba Infucare Rx Of Md
IS A REGISTERED **Active**
License Expiration Date
Pharmacy Waiver 05/31/2026

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
PW0521	05/31/2026

SIGNATURE OF BEARER

168640

168640

State of Maryland

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT **Factor One Source Pharmacy Llc Dba Infucare Rx Of Md**
IS A REGISTERED **Active**
License Expiration Date
Pharmacy Waiver 05/31/2026

SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
PW0521	**05/31/2026**

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Details

Demographic Information

Name: FACTOR ONE SOURCE PHARMACY LLC dba INFUCARE RX OF MD

Address Information

Address: 217 Glenn Street
Suite #300

City: Cumberland **State:** MD **Zip:** 21502

Maryland License\Permit Information

Number: PW0521 **Type:** Pharmacy Waiver **Subtype:** Home Infusion **Status:** Active

Original Issued: 12/27/2018 **Date Renewed:** 4/24/2024 **Expires:** 5/31/2026

No Speciality Information

Board Orders

Clicking on the corresponding link will allow documents to be viewed.

No Related Documents

****Please refer to the Board's Formal Disciplinary Action page for the listing of all disciplinary actions.****

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FF8097239	09-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-20-2024

FACTOR ONE SOURCE PHARMACY LLC
DBA INFUCARE RX OF MD
217 GLENN ST STE 300
CUMBERLAND, MD 215022590

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FF8097239	09-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-20-2024

FACTOR ONE SOURCE PHARMACY LLC
DBA INFUCARE RX OF MD
217 GLENN ST STE 300
CUMBERLAND, MD 215022590

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4FFF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 04203		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: HomeCare Rx, Inc. dba InfuCare Rx of NJ

Physical Address: 45 Route 46, Unit 610

City: Pine Brook State: NJ Zip: 07058

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-920-2090 Toll Free # (NAC 639.708, NRS 639.23286): 877-920-2090

Fax: 877-920-0466 Contact Email: licensing@infucarerx.com

Website: www.infucarerx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Ami D. Patel

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22188

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Ami D. Patel	NV Pharmacist Registration #: 22188
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NJ

Parent Company (if any): InfuCare Rx, Inc.

Corporation/Organization Name: HomeCare Rx, Inc. dba InfuCare Rx of NJ

Mailing Address: 45 Route 46, Unit 610

City: Pine Brook State: NJ Zip: 07058

Telephone: 877-828-3940 Email: Licensing@infucarerx.com

Contact Person Name: Jessica Seefried

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Corporate Secretary and General Counsel (title) for HomeCare Rx, Inc. dba InfuCare Rx of NJ (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Tiffany Scheppers

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/19/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ami D. Patel hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for HomeCare Rx, Inc. dba InfuCare Rx of NJ (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Ami Patel

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 12th day of November, 2025

Notary Public

CATHERINE G. MOYLES
Notary Public
State of New Jersey
My Commission Expires July 23, 2028
I.D.# 50086730

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/19/2025

Date

Board Use Only	Date Received: 12/8/25	Amount: $500 CK 1000007477

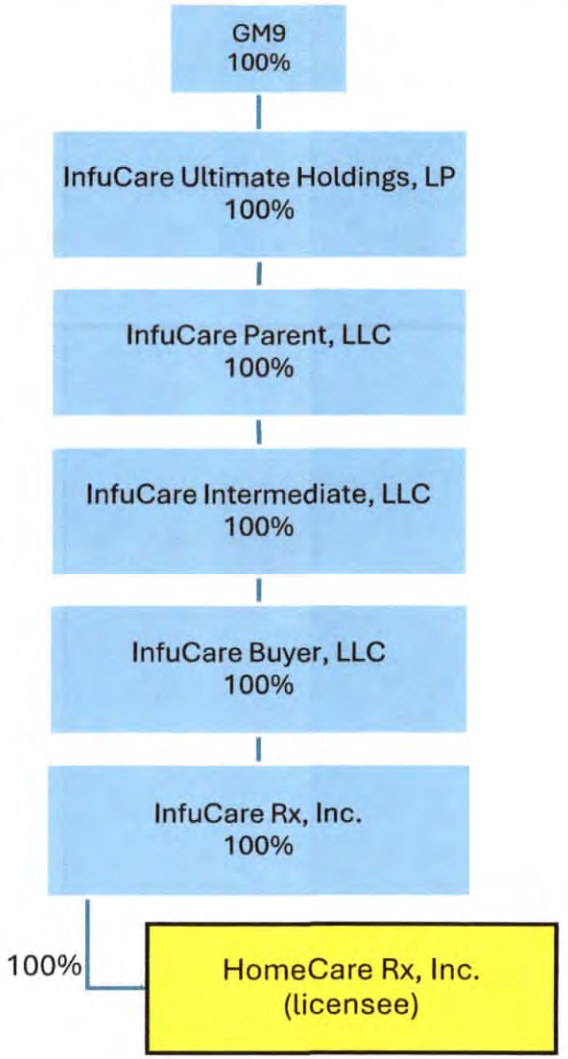
Corporate Officers			
Name	**Title**	**Address**	**Phone**
Dhara Patel	President, Director, and Treasurer	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940
Tiffany Scheppers	Secretary and General Counsel	695 US Hwy 46, STE 100, Fairfield, NJ 07004	877-828-3940

Pre- and Post- Sale for HomeCare Rx, Inc.

Pre-Close Structure



Post-Close Structure



HomeCare Rx, Inc. DBA InfuCare Rx of NJ			
45 Route 46, Unit 610, Pine Brook, NJ 07058			
List of Shareholders			
Name	**Address**	**Phone**	**Percent Ownership**
InfuCare Rx, Inc.	695 US Highway 46, Suite 100, Fairfield, NJ 07004	877-828-3940	100%

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

HOMECARE RX INC
0400722426

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on February 06, 2015.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 14th day of October, 2025

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6169500142

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: HomeCare Rx, Inc. dba InfuCare Rx of NJ

Pharmacy/Wholesaler License # (if applicable): PH04203

Physical Address: 45 Route 46, Unit 610

City: Pine Brook State: NJ Zip: 07058

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-920-2090 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Ami Middle: Dinesh Last: Patel

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Addres[redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. Louis College of Pharmacy		08/04 - 05/10	
Address	City	State	Zip
1 Pharmacy Place	St. Louis	MO	63110
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Shawnee Mission Northwest		08/00 - 05-04	
Address	City	State	Zip
12701 W 67th St	Shawnee	KS	66216
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/25-present	[redacted]			
06/18 - 10/25				
11/12 - 06/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
HomeCare Rx, Inc. dba InfuCare Rx of NJ			12/2015 - Present
Business Address	**City**	**State**	**Zip**
45 Route 46, Unit 610	Pine Brook	NJ	07058
Phone	**Title**		**Number of Employed Hours**
877-920-2090	PIC		28,856
Description of Duties			
For pharmacist in charge role, making sure pharmacy is adhering to rules and regulations; maintain close control over pharmacy operations; managing all pharmacists and technicians on staff.			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Ami Dinesh Patel, **certify that as the designated representative for**

HomeCare Rx, Inc. dba InfuCare Rx of NJ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AP I am at least 21 years of age;
3. AP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ami Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/12/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ami Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-12-25

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Essex

I, Ami Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-12-25

Date

Subscribed and Sworn to before me this 12th day of November 2025.

Notary Public Signature

CATHERINE G. MOYLES
Notary Public
State of New Jersey
My Commission Expires July 23, 2028
I.D.# 50086730

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site HomeCare Rx, Inc. dba InfuCare Rx of NJ

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04203

Physical Address 45 Route 46, Unit 610

City Pine Brook State NJ Zip 07058

Mailing Address (if different from physical address) P.O. Box 2578

City Secaucus State NJ Zip 07096

Telephone 877-920-2090 Website www.infucarerx.com

Licensing Company Email licensing@infucarerx.com

Section 2: Personal Information

First Dhara Middle Devendra Last Patel

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Armstrong Atlantic State University		Unknown	
Address	**City**	**State**	**Zip**
11935 Abercorn St.	Savannah	GA	31419
Diploma/Degree obtained, if any			
Bachelors Degree in Liberal Arts			

School Name		From - To (MM/YY – MM/YY)	
Richmond Hill High School		Unknown	
Address	**City**	**State**	**Zip**
Unknown			
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Unknown-Present	[redacted]			
Unknown-Present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
InfuCare Rx, Inc.			Present	
Business Address		**City**	**State**	**Zip**
695 US Hwy 46, STE 100		Fairfield	NJ	07004
Phone	**Title**			
877-828-3940	President			
Description of Duties				
President of InfuCare Rx, Inc.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dhara Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Passaic

I, Dhara Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/2/2025

Date

Subscribed and Sworn to before me this 2nd day of December, 2025

Notary Public Signature

DANIEL ALBARRAN
Notary Public, State of New Jersey
My Commission Expires Dec 15, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: HomeCare Rx, Inc. dba InfuCare Rx of NJ

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04203

Physical Address: 45 Route 46, Unit 610

City: Pine Brook State: NJ Zip: 07058

Mailing Address (if different from physical address): P.O. Box 2578

City: Secaucus State: NJ Zip: 07096

Telephone: 877-920-2090 Website: www.infucarerx.com

Licensing Company Email: licensing@infucarerx.com

Section 2: Personal Information

First: Tiffany Middle: Samantha Last: Scheppers

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: NC Zip: 28173

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri St Louis		Unknown	
Address	**City**	**State**	**Zip**
1 University Blvd.	St. Louis	MO	63121-4400
Diploma/Degree obtained, if any			
MBA not completed			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University School of Law		8/1996-5/1999	
Address	**City**	**State**	**Zip**
100 N Tucker Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
St. Louis University		8/1993-5/1999	
Address	**City**	**State**	**Zip**
1 N Grand Blvd	St. Louis	MO	63101
Diploma/Degree obtained, if any			
Nursing			

School Name		From - To (MM/YY – MM/YY)	
Cornelia Connelly School of the Holy Child Jesus		1984-1988	
Address	**City**	**State**	**Zip**
2323 W Broadway	Anaheim	CA	92804
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY) 8/2015-present	[redacted]			
From - To (MM/YY – MM/YY) 3/2013-8/2015				
From - To (MM/YY – MM/YY) 1/2000-3/2013				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Infucare Rx Inc.			03/2021 - Present
Business Address	**City**	**State**	**Zip**
695 US Hwy 46, STE 100	Fairfield	NJ	07004
Phone	**Title**		
877-327-8881	General Counsel and Corporate Secretary		

Description of Duties

Oversee all corporate, regulatory, employment, litigation, and compliance legal matters.

Business Name			From - To (MM/YY – MM/YY)
Asembia, LLC			07/2019 - 12/2020
Business Address	**City**	**State**	**Zip**
200 Park Ave #300	Florham Park	NJ	07932
Phone	**Title**		
973-564-8004	Senior Vice President, General Counsel and Chief Compliance Officer; Corporate Secretary		

Description of Duties

Oversee all corporate, regulatory, employment, litigation, and compliance legal matters; Current Officer acting as Corporate Secretary; Advised executive leadership and Board of Directors on complex regulatory compliance matters.

Business Name			From - To (MM/YY – MM/YY)
Outside General Counsel			03/2019 - 07/2019
Business Address	**City**	**State**	**Zip**
	Charlotte	NC	
Phone	**Title**		
314-808-3974	Outside General Counsel		

Description of Duties

Delivered outsourced general counsel and compliance services to, and temporary coverage for, in-house general counsel and chief compliance officer clients, re: health care, pharma, biotech and CRO/CSO companies on legal and regulatory.

Business Name			From - To (MM/YY – MM/YY)
SYNEOS HEALTH, INC			08/2012 - 03/2019
Business Address	**City**	**State**	**Zip**
1030 Sync Street	Morrisville	NC	27560
Phone	**Title**		
919-876-9300	Senior Associate General Counsel & Chief Compliance Officer; Commercial Division		

Description of Duties

Supervised legal and compliance teams across US, Canada, Europe and APAC, reporting directly to the General Counsel.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tiffany Scheppers

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Mecklenburg

I, Tiffany Scheppers, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2025

Date

Subscribed and Sworn to before me this 19 day of Nov 2025

Notary Public Signature

NIMESH R. PATEL NOTARY PUBLIC MECKLENBURG COUNTY, N.C.

My Commission Expires
Nov 7, 2029

(Seal)

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
PO BOX 45013
NEWARK, NJ 07101

MATTHEW J. PLATKIN
Attorney General

ELIZABETH M. HARRIS
Acting Director

October 29, 2025

Ami D. Patel, RPIC
Homecare Rx, Inc dba InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058

Re: Inspection Report # 8-6531-25-1568
License # 28RS00739900

Dear Licensee:

Per your request, please find attached a copy of the New Jersey Board of Pharmacy (the "Board") inspection report for the pharmacy listed above. Because the Board may not have yet had the opportunity to review this report, please be aware the Board may determine that violations of law have occurred and determine to impose fines and penalties at a future date.

In addition, this report may contain confidential patient or licensee information. Before further distributing this report, please ensure that you are complying with laws regarding HIPAA requirements and those protecting Personally Identifiable Information (PII).

Sincerely,

Charles Akpan
Agency Services Representative
New Jersey Board of Pharmacy

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Enforcement Bureau
124 Halsey Street, 3rd Floor, Newark NJ 07102

MATTHEW J. PLATKIN
Attorney General

ELIZABETH HARRIS
Acting Director

Mailing Address:
P.O. Box 45022
Newark, NJ 07101
(973) 504-6300

Anthony Rubinaccio, Executive Director
Board of Pharmacy

RE: AMI PATEL, RPIC
HOMECARE RX INC. DBA INFUCARE RX
OF NJ-PINE BROOK
ASSIGNMENT# 8-6531-25-1568

Dear Mr. Rubinaccio,

Enclosed is a copy of a Report of Inspection, which is forwarded for Board review. This above captioned matter was assigned to Section 2 and I approved the report.

This assignment is now closed. No further action will be taken by the Bureau unless a new request is received.

Very Truly Yours,

Tony H. Qi

Tony H.Qi, Supervising Investigator
Section # 2

cc: Board of Pharmacy

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STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
ENFORCEMENT BUREAU

REPORT OF INSPECTION

To:	ASSIGNMENT #	DATE:	INSPECTION DATE:
Board of Pharmacy	8-6531-25-1568		10/10/2025
SUBJECT(S):		By: Donna Kapetanakis, RPh	

AMI PATEL, RPIC
License # 28RI03544600 (Exp. 04/30/2027)
HOMECARE RX INC. DBA INFUCARE RX OF NJ
Permit # 28RS00739900 (Exp. 06/30/2026)
45 US-46 #610
Pine Brook, New Jersey 07058
(877) 920-2090
CDS REG#: D10573100 (Exp. 10/31/2025)
DEA REG#: [redacted] (Exp. 10/31/2026)

REFERENCE:

Board of Pharmacy inspection activity conducted pursuant to N.J.S.A. 45:1-18 and N.J.S.A. 45:14-48(a)ll &12.

DETAILS:

On October 10, 2025, Bureau Investigator Donna Kapetanakis visited the SUBJECT pharmacy department for the purpose of engaging in a Board of Pharmacy Inspection (BOP) activity in response to the sterile compounding room that had sustained water damage. The following information is provided for your review and appropriate action.

SUBJECT PHARMACY DEPARTMENT:

TYPE: Closed Door Home Infusion, Specialty Medication Pharmacy that compounds medium to low risk sterile preparations, specifically TPNs and antibiotics.

LOCATION: Corporate.

OWNERSHIP: HomeCare Rx, INC., Corporation Service Company- Princeton.

ADDITIONAL PHARMACIES: Yes. InfuCare Rx, Aston, PA, Cumberland, MD, Glendale, CA, Irving, TX, Kenner, LA, West Palm Beach, FL

BUSINESS MODEL: The SUBJECT pharmacy provides access to specialty medications, delivered directly to the patients home.

BUSINESS HOURS: Weekdays: Monday – Friday 9:00 A.M. to 5:30 P.M.; Saturday and Sunday Closed.

TELEMEDICINE / TELEPHARMACY PLATFORMS: No.

CENTRAL FILL AGREEMENTS/SHARED SERVICES: No.

OTHER BUSINESS AT SAME ADDRESS: No.

RX/DAY/WEEK: Approximately five hundred - six hundred (500-600) prescriptions weekly.

NON-PATIENT SPECIFIC RX: No.

REVERSE DISTRIBUTOR: Inmar

PHARMACY SOFTWARE: CPR+/Wellsky

EMR PLATFORMS: CPR+/Wellsky/ Infucare Rx Health Hub (Proprietary Software)

AUTOMATED DISPENSING/COUNTING MACHINE(S): No.

OFFICE OF WEIGHTS/MEASURES: Compliant.

PMP REPORTING: PMP Waiver, expires 6/30/2026.

WHOLESALER(S)/MEDICATION PLATFORM(S): Amerisource/Cencora, ASD, Baxter, BioCare SD, Biologix Direct, Cardinal Specialty, CuraScript SD, Genentech, Integrated Medical Sysytems (IMS), McKesson Specialty, McKesson Supply Manager, Moog Medical Devices, Preferred Medical, Pfizer, Progressive Medical, Right Way Medical, Sanofi-Aventis, Takeda, Uline, Vygon.

BUYING GROUP/CO-OP MEMBERSHIP: Primary GPO is Vizient, also contracted with MHA, Asembia, Premier/Innovatix and Matrix.

CDS INVENTORY: Compliant zero reported conducted on 02/28/2025.

CDS STORAGE: NO CDS medications.

VETERINARY MEDS: No

COMPOUNDING: Yes, Sterile Non-Hazardous Compounding.

TEMPERATURE RECORDS / POLICIES AND PROCEDURES: Compliant.

COMPLIANCE PACKAGING: No.

SERVICE TO GROUP HOMES/NURSING HOMES/DAYCARE CENTERS: No

DELIVERY: Yes. FedEx.

SIGNAGE/HOURS: Compliant.

SECURITY: Compliant. ADT, Battery Backup- 48 hours.

REMOTE PROCESSING: No

NON-RESIDENT PHARMACY PERMITS: Yes, (Exhibit #1).

NALOXONE PILOT PROGRAM: No.

ACCREDITATIONS: ACHC SRX- EXP 01/25/2028, ACHC HIT- EXP 01/21/2026, URAC Specialty Pharmacy- EXP 08/01/2027.

WAIVERS FROM THE BOARD OF PHARMACY: Yes, PMP Waiver, compliant.

PERSONNEL:

Pharmacist-In-Charge: Ami Patel (28RI03544600).

Ms. Patel was present and in practice during the inspection. For identification purposes, all pharmacy personnel who were present completed respective "Pharmacy Personnel Identification" forms (**Attachment A, pages 1-21**).

PHARMACIST/TECHNICIAN RATIO: Non-Compliant, 6 pharmacists and 15 technicians.

GENERAL REQUIREMENTS SURVEY: Compliant (**Attachment A, page 22**)

INVENTORY: Compliant. Inspection of the pharmacy's "active" drug stock inventory did not identify deficiencies (Form EB-23A Inventory Quality Assurance Examination) (**Attachment A, page 23**).

DEFICIENCIES: The following deficiencies were noted during the inspection.

[13:39-6.15] Pharmacist shall not supervise more than two (2) pharmacy technicians at any given time.

Fifteen (15) pharmacy technicians were not PTCB Nationally certified, and six (6) pharmacists, which exceeds the (2:1) ratio.

MISCELLANEOUS:

This investigator observed a compounding pharmacy technician demonstrate the hand hygiene and garbing process. The compounding pharmacy technician verbally explained the compounding process to this investigator once the compounder donned gloves, because the SUBJECT pharmacy had no active orders for compounded sterile preparations (CSPs) during the inspection. The compounding pharmacy technician told me that the pharmacist checked the final product on a "black and white background" for any particles.

The SUBJECT pharmacy will be compounding low to medium-risk level antibiotics and TPNs. The RPIC stated that the pharmacy does not assign an extended BUDs to finished compounds. The SUBJECT pharmacy does not engage in high-risk compounding. The SUBJECT pharmacy will not be compounding batch preparations.

During the inspection, two (2) training files were reviewed, including didactic training, gloved/fingertip sampling, and aseptic technique for the pharmacist-in-charge, Ami Patel, and a compounding pharmacy technician, Marian Abdelshahid (28RW003396400). The training records were in compliance.

Temperature, Pressure, and Humidity were continuously monitored and documented via"Simplifi". The pressure gauge was alarmed. The logs were obtained and reviewed, and no discrepancies were identified.

Cleaning and disinfection have also been conducted and documented via "Simplifi" and appear to be consistent with the regulations set forth in N.J.A.C. 13:39-11.16.

Evaluation of the SUBJECT pharmacy's sterile compounding practice per N.J.A.C. Subchapter 13:39-11 was conducted. Categories are summarized below:

- Cleaning Records: Compliant
- In-House Surface: Compliant
- Certification Reports: Compliant, March 2025 and September 2025
- Training: Compliant, PIC Ami Patel 28RI03544600 Marian Abdelshalid 28RW03396400
- Label and Compounding Records: Compliant
- Process: Compliant- Garbing and Gowning observed Marian Abdelshalid 28RW03396400

EXIT BRIEFING:

Prior to departing from the SUBJECT pharmacy department, I conducted an exit briefing with Ms. Patel. In connection with the exit briefing, I completed a Form EB-33 (**Attachment A, page 24**) Report of Inspection and explained to her the deficiencies that had been noted.

Ms. Patel was given the opportunity to make any comments, corrections, or explanations to the deficiency noted in this report. After Ms. Patel was satisfied and understood the deficiency noted, she signed off on the Form EB-33 report as well as on the attached Form EB-23A and Form EB-02. I then departed from the SUBJECT pharmacy.

This assignment is now closed. No further action will be taken by the Bureau unless a new request is received.

CERTIFICATION:

I, the undersigned, of full age, employed by the State of New Jersey, Division of Consumer Affairs, Enforcement Bureau- Professional Boards as an Investigator, certify that all of the information contained in this report based upon my personal knowledge is true. I am aware that if any of the information is willfully false, I am subject to punishment. With respect to the information reported by me, which the context discloses is not based on my personal knowledge, I certify that I have reported in good faith and, to the best of my recollection, an accurate account of the information reported to me.

Donna Kapetanakis, R.Ph.

Donna Kapetanakis, R.Ph., Investigator

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Ahanda, AZ 00501
Rx #: 285524 Date Dispensed: 10/10/25
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

P. Test, MD
NDC: 53808-0230-30
(10/10/25)
Mfr: Nurse Assist, LLC

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Ami Patel

INITIALS: AP

PRINT NAME: Ami Patel

LICENSE/REGISTRATION #: 28RI03544600

HOME ADDRESS: [redacted]

CITY, STATE, ZIP North Caldwell, NJ 07006

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: Dec 2015

JOB DESCRIPTION: PIC

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00501

P. Test, MD
NDC: 52805-0280-X

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard ramainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [signature]

INITIALS: RP

PRINT NAME: RAJIV PATEL

LICENSE/REGISTRATION #: 28 RI027 18300

HOME ADDRESS: [redacted]

CITY, STATE, ZIP RIVERDALE, NJ 07457

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 5/2025

JOB DESCRIPTION: Pharmacist

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Alhanda, AZ 00501

P. Test, MD
NDC: 52806-0230-00

Rx #: 285524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [signature]

INITIALS: MN

PRINT NAME: Mariam Nicola

LICENSE/REGISTRATION #: 28RI03408600

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Bridgewater NJ 08807

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 10/21/24

JOB DESCRIPTION: staff pharmacist

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref P_Test, MD
123 Main street Abanda, AZ 00501 NDC: 63605-0338-03
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Elizabeth Gethahun

INITIALS: EG

PRINT NAME: ELIZABETH GETTACHEW

LICENSE/REGISTRATION #: 28RT02143700

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Hackensack, NJ 07601

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40 hrs

DATE OF EMPLOYMENT:

JOB DESCRIPTION: Pharmacist

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00601
P. Test, MD
NDC: 52606-0332-30
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Thomas J McCaa

INITIALS: TJM

PRINT NAME: THOMAS J MCCAA

LICENSE/REGISTRATION #: 28RI03745000

HOME ADDRESS: [redacted]

CITY, STATE, ZIP BROOMALL, PA 19008

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 1-27-22 → PRESENT

JOB DESCRIPTION: PHARMACY MANAGER

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abands, AZ 00501
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/26)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

P. Test, MD
NDC: 52000-0230-30

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, **Staff pharmacist**, Pharmacy technician, Supportive personnel)

SIGNATURE: Pinal Patel

INITIALS: PP

PRINT NAME: Pinal Patel

LICENSE/REGISTRATION #: 28RI03752700

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Secaucus, NJ 07094

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 7/6/16

JOB DESCRIPTION: Staff Pharmacist

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2080

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ00501

P. Test, MD
NDC: 52606-0230-00

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Daniel Burges

INITIALS: DB

PRINT NAME: Daniel Burges

LICENSE/REGISTRATION #: 28RW06018900

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Morristown NJ 07960

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 9-24-25

JOB DESCRIPTION: P.S.R

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00501
P. Test, MD
NDC: 52806-0230-00
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: ajiii

INITIALS: AC

PRINT NAME: Alfonso Cejigas

LICENSE/REGISTRATION #: 28RW04985700

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Belleville, NJ, 0719

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40hrs

DATE OF EMPLOYMENT: 09/30/2025

JOB DESCRIPTION: Pharmacy technician

Photo copy Polaroid Wallet Size Standard

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00501

P. Test, MD
NDC: 52609-0250-00

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Directions: Mfr: Nurse Assist, LLC
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [signature]

INITIALS: MEP

PRINT NAME: MIAMIN E Perez

LICENSE/REGISTRATION #: 28RW02358900

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Clifton NJ 07012

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40-hr

DATE OF EMPLOYMENT: 5/2023

JOB DESCRIPTION: Pharmacy Tech

Change name and address updated to Board

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00501

P. Test, MD
NDC: 52806-0330-00

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/26)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [signature]

INITIALS: KA

PRINT NAME: Kendrick Abraham

LICENSE/REGISTRATION #: 28AI03948200

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Linden, NJ, 07036

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 9/3 12019

JOB DESCRIPTION: Pharmacy Technician

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

P. Test, MD
NDC: 52606-0230-00

Test patient, Test ref
123 Main street Abanda, AZ 00501
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [redacted]

INITIALS: MA

PRINT NAME: Maisoon Abdelkhalid

LICENSE/REGISTRATION #: 28RW03396400

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Rutherford NJ 07070

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40 hours

DATE OF EMPLOYMENT: 08/19/2026

JOB DESCRIPTION: Pharmacy Technic

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9380
877-920-2090

DATE: 10/10/25

P. Test, MD
NDC: 52868-0230-00

Test patient, Test ref
123 Main street Abanda, AZ 00501
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nursa Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, **Pharmacy technician**, Supportive personnel)

SIGNATURE: Mlambon

INITIALS: ML

PRINT NAME: Myra Lambon

LICENSE/REGISTRATION #: 28RW00338500

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Belleville NJ 07109

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH: [redacted]

HOURS EMPLOYED WEEKLY: 40 hrs

DATE OF EMPLOYMENT: July 15, 2024

JOB DESCRIPTION: Pharmacy Technician

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00601

P. Test, MD
NDC: 52808-0230-00

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Fouad Faragalla

INITIALS: FF

PRINT NAME: Fouad Faragalla

LICENSE/REGISTRATION #: 28RI03849000

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Paramus NJ 07652

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 4/7/2025

JOB DESCRIPTION: pharmacist

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abends, AZ 00501

P. Test, MD
NDC: 52604-0230-00

Rx #: 285524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [signature]

INITIALS: MC

PRINT NAME: Marife Cruz

LICENSE/REGISTRATION #: 28RW02585400

HOME ADDRESS: [redacted]

CITY, STATE, ZIP New Jersey

TELEPHONE NUMBER: [redacted]

EMAIL: mcruz1@[redacted]

DATE OF BIRTH: [redacted]

HOURS EMPLOYED WEEKLY: 40 hours

DATE OF EMPLOYMENT: Oct 17, 2022

JOB DESCRIPTION: Pharmacy technician

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

P. Test, MD
NDC: 52808-023-0-00

Test patient, Test ref
123 Main street Alaska, AZ 00501
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [signature]

INITIALS: KLM / km

PRINT NAME: KHARISMA LEI D. MONTEGRANDE

LICENSE/REGISTRATION #: 28RW02047200 / 30129072 - CPHT

HOME ADDRESS: [redacted]

CITY, STATE, ZIP PARSIPPANY, NJ 07054

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40 HRS

DATE OF EMPLOYMENT: APRIL 4, 2022

JOB DESCRIPTION: PHARMACY TECHNICIAN

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00501

P. Test, MD
NDC: 52606-0252-00

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE:	OMAR NARRO
INITIALS:	O.N.
PRINT NAME:	OMAR NARRO
LICENSE/REGISTRATION #:	28RW01909900
HOME ADDRESS:	[redacted]
CITY, STATE, ZIP	ELMWOOD PARK NJ 07407
TELEPHONE NUMBER:	[redacted]
EMAIL:	
DATE OF BIRTH:	
HOURS EMPLOYED WEEKLY:	40
DATE OF EMPLOYMENT:	08/19/2024
JOB DESCRIPTION:	PHARMACY TECHNICIAN

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00601
P. Test, MD
NDC: 52605-C23C-00
Rx #: 265524 Date Dispensed: 10/10/25 (10/10/26)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Jasmine Green

INITIALS: JG

PRINT NAME: Jasmine Green

LICENSE/REGISTRATION #: 28RN02727500

HOME ADDRESS: [redacted]

CITY, STATE, ZIP East Hanover, NJ 07936

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 2/2025

JOB DESCRIPTION: pharmacy technician (PSR)

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00601

P. Test, MD
NDC: 52708-4230-30

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, (Pharmacy technician), Supportive personnel)

SIGNATURE:

INITIALS: EP

PRINT NAME: EMILIO PORTO

LICENSE/REGISTRATION #: 25RW00156200

HOME ADDRESS: [redacted]

CITY, STATE, ZIP NUTLEY, NJ 07110

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40 HRS

DATE OF EMPLOYMENT: 4-10-23

JOB DESCRIPTION: PHARMACY TECH

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00501

P. Test, MD
NDC: 52605-0230-30
(10/10/25)

Rx #: 265524 Date Dispensed: 10/10/25 Qty: 1
Sodium Chloride 0.9% 10mL Flush Syringe
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Sadé McMoore

INITIALS: SM

PRINT NAME: Sadé McMoore

LICENSE/REGISTRATION #: 28RW00479300

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Hillside, NJ, 07205

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40hrs

DATE OF EMPLOYMENT: November 25, 2024

JOB DESCRIPTION: Pharmacy Technician (PSR)

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abenda, AZ 00601

P. Test, MD
NDC: 52808-233-00

Rx #: 285524 Date Dispensed: 10/10/25 (10/10/26)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: [signature]

INITIALS: MP

PRINT NAME: MEENA G PATEL

LICENSE/REGISTRATION #: 28RW02893100 8/31/26

HOME ADDRESS: [redacted]

CITY, STATE, ZIP ROCKAWAY

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: AUG-26-24

JOB DESCRIPTION: Pharmacy Technician

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL
DIVISION OF CONSUMER AFFAIRS

BOARD OF PHARMACY/ENFORCEMENT BUREAU

PHARMACY PERSONNEL IDENTIFICATION FORM

InfuCare Rx of NJ
45 Route 46, Unit 610
Pine Brook, NJ 07058-9390
877-920-2090

DATE: 10/10/25

Test patient, Test ref
123 Main street Abanda, AZ 00501

P. Test, MD
NDC: 52603-0230-00

Rx #: 265524 Date Dispensed: 10/10/25 (10/10/25)
Sodium Chloride 0.9% 10mL Flush Syringe Qty: 1
Mfr: Nurse Assist, LLC
Directions:
Flush IV Catheter with 5 -10mL Sodium Chloride 0.9%
Before and after each dose of medication.
Discard remainder of syringe after single use.
*** Saline, Medication, Saline***

Storage: Room Temperature
Use By: 04/08/26 RPh: PP
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

INDICATE POSITION (Pharmacist-In-Charge, Staff pharmacist, Pharmacy technician, Supportive personnel)

SIGNATURE: Nirav Damani

INITIALS: ND

PRINT NAME: NIRAVKUMAR DAMANI

LICENSE/REGISTRATION #: 10066043

HOME ADDRESS: [redacted]

CITY, STATE, ZIP Montville NJ-07045

TELEPHONE NUMBER: [redacted]

EMAIL:

DATE OF BIRTH:

HOURS EMPLOYED WEEKLY: 40

DATE OF EMPLOYMENT: 11/18/2024

JOB DESCRIPTION: Pharmacy Tech

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: 10/10/2025
File number: ~~8-6531~~-25-1568

1 of 3

Board of Pharmacy Inspection Report

Home Care Rx Inc DBA Infucare Rx of NJ
Pharmacy trade name / Corporation name (if not the same)

96 US-46 Suite 610
Owner (as identified on the occasion of this inspection)
Street address
Pine Brook NJ 07058
City State ZIP code

SEE personnel forms
(Paste pharmacy label here)

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]
Home Care Rx Inc DBA Infucare Rx of NJ — 28RS00739900 — 6-30-26
Name of permit holder — Certificate number — Expiration date

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]
D 10573100 — 10/31/25
Certificate number — Expiration date

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]
[redacted] — Expiration date

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-6.3(c)]

A. Pharmacist-in-charge's name (please print): Ami Patel
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☑ Yes ☐ No)

28RI03544600 — 4-30-27 — 40
Permit number — Expiration date — Hours worked per week

1. Is the registered pharmacist-in-charge's current renewal on display? ☑ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
[Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☐ Yes ☑ N/A DLS

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
			☐ Yes ☐ No	
			☐ Yes ☐ No	
SEE ATTACHED			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.8(a)3 and 13:39-5.6]

1. Is there a sink with hot and cold running water? ☑ Yes ☐ No
2. Is there a satisfactory counting tray or device? ☑ Yes ☐ No

IV. Miscellaneous requirements

1. [16 C.F.R. 1700.14/15] Is a representative inventory of safety closures present? ☑ Yes ☐ No
2. Are prescriptions being dispensed in containers with an appropriate safety closure? ☑ Yes ☐ No
3. [N.J.A.C. 13:39-5.8(c)] Is the dispensing area in a clean, orderly and sanitary condition? ☑ Yes ☐ No
4. [N.J.S.A. 45:14-48a(10)] [N.J.A.C. 13:39-5.8(a)1] Is the pharmacy library satisfactory? ☑ Yes ☐ No
5. [N.J.A.C. 13:45H-5.7] Has the required biennial C.D.S. inventory been conducted? ☑ Yes ☐ No 12/28/25 PHP waiver exp 6/30/26
6. [N.J.A.C. 13:45H-5.5] Has the C.D.S. inventory been properly documented? ☑ Yes ☐ No

Ami Patel — Ami Patel
Print the name of the registered pharmacist who was present for the survey — Signature of the registered pharmacist who was present for the survey

Signature of Investigator(s) conducting the survey

Form EB-02 (10/12)

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

2053

Pharmacy: HomeCare Rx Inc. DBA Infucare Rx of NJ Date: 10/10/2025

Street Address: 45 US 46 Suite #610

City, State, ZIP: Pine Brook, NJ 07058

Kapetanakis
Inspector

The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.

Initials of Registered Pharmacist	Quantity or Commercial Package Size	Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Deficiencies [13:39-7.18] [13:39-6.2(f)7] Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
		Totals from above										
		Collective Totals from other pages										
		Composite Total on this page										

Random Shelves Checked - No deficiencies

COMMENTS:

I hereby acknowledge and attest to the accuracy of the inventory deficiencies reported above.

Ami Patel
PRINTED NAME OF PHARMACIST

SIGNATURE OF PHARMACIST

:B-23A (1/05)

Date: 10/10/25
Time entered: 10:30 am
Time departed: 2:10 pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

This section is required: Page 3 of 3

Name of Pharmacy: HomeCare Rx Inc DBA Infucare Rx of NJ
Address: 45 US-46 Suite #610 Pine Brook, NJ 07058
Name and registration number of pharmacist-in-charge:
Ami Patel RPIC 28RI03544600
(If the Pharmacist-in-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty.)

The following deficiencies have been noted: Routine Inspection

13:39-6.15 Pharmacist shall not supervise more than two (2) pharmacy technicians @ any given time.
- 6 RPh
- 15 Techs

Upon further review of documents obtained by this investigator further deficiencies maybe noted subsequent to the inspection activity.

* Refrigerators & Pharmacy Dispensing area temperature logs are being emailed to this Investigator
* 2 months Temp logs all Refrigerators and pharmacy dispensing area

* To Be reviewed *

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS:

Ami Patel
(Signature of the Pharmacist identified above)

I-33

3/07

Branch	State	License Type	License Number	Issue Date	Expiration Date
[redacted]	ALABAMA	Non-Resident Pharmacy	115174	3/6/2023	12/31/2026
	ALASKA	Out-of-State Pharmacy	231870	11/19/2024	6/30/2026
	ARIZONA	Pharmacy - Independent Mail Order	Y007544	3/30/2018	10/31/2027
	ARKANSAS	Retail Pharmacy	OS03280	9/25/2024	12/31/2025
	COLORADO	Prescription Drug Outlet-Out-of-State	OSP.0007126	11/1/2018	10/31/2026
	CONNECTICUT	Non-Resident Pharmacy	PCN.0003555	9/1/2019	8/31/2026
	DEA	DEA	[redacted]	9/24/2020	10/31/2026
	DELAWARE	Non-Resident Pharmacy	A9-0002100	11/29/2017	9/30/2026
	DISTRICT OF COLUMBIA	Non-Resident Pharmacy	NRX240001264	5/23/2024	5/31/2027
	FLORIDA	Non-Resident Pharmacy	PH30327	8/24/2016	2/28/2027
	GEORGIA	Non-Resident Pharmacy	PHNR001008	10/7/2016	6/30/2027
	HAWAII	Miscellaneous Permit	PMP-1999	2/3/2023	12/31/2025
	IDAHO	Nonresident Drug Outlet	NDO74856	3/29/2024	12/31/2025
	ILLINOIS	Pharmacy	054.021789	4/6/2021	3/31/2026
	INDIANA	Non-Resident Pharmacy	64003744A	5/30/2025	12/31/2025
	IOWA	Non-Resident Pharmacy	5580	2/14/2023	12/31/2025
	KANSAS	Non-Resident Pharmacy	22-116844	1/4/2022	6/30/2026
	KENTUCKY	Non-Resident Pharmacy	NJ2489	3/14/2019	6/30/2026
	LOUISIANA	Non-Resident Pharmacy	PHY.007904-NR	5/22/2019	12/31/2025
	MAINE	Mail Order Pharmacy	MO40003564	10/25/2024	12/31/2025
	MARYLAND	Pharmacy	P07660	10/4/2017	5/31/2026
	MASSACHUSETTS	Non-Resident Retail Pharmacy	NDS31528	2/5/2025	12/31/2025
	MICHIGAN	Pharmacy	5301013342	9/4/2024	9/4/2026
	MICHIGAN	Controlled Substance License	5315246873	9/4/2024	9/4/2026
	MINNESOTA	Pharmacy	266921	5/24/2024	6/30/2026
	MISSISSIPPI	Non-Resident Pharmacy	17434/7.1	1/8/2019	12/31/2025
	MISSOURI	Pharmacy - Class A	2017011172	4/11/2017	10/31/2027

[redacted]	MONTANA	Mail Order Pharmacy	PHA-MOP-LIC-111834	1/10/2025	11/30/2026	
	NEBRASKA	Mail Service Pharmacy	1894	2/13/2025	7/1/2026	
	NEVADA	Pharmacy	PH04203	3/23/2020	10/31/2026	
	NEW HAMPSHIRE	Non-Resident Pharmacy	NR1389	9/12/2016	12/31/2025	
	NEW JERSEY	Pharmacy	28RS00739900	4/15/2015	6/30/2026	
	NEW JERSEY	Controlled Dangerous Substance (CDS)	D10573100	10/9/2020	10/31/2026	
	NEW MEXICO	Non-Resident Pharmacy	PH00005874	11/1/2024	12/31/2026	
	NEW YORK	Non-Resident Establishment Registered Pharmacy	034296	1/27/2016	12/31/2027	
	NORTH CAROLINA	Pharmacy	14844	12/30/2021	12/31/2025	
	NORTH DAKOTA	Class G - Out of State	Phar2231	1/17/2025	6/30/2026	
	OHIO	Terminal - Non-Resident Pharmacy - Category 2	022863850	3/1/2018	3/31/2027	
	OKLAHOMA	Non-Resident Pharmacy	99-9666	4/5/2024	4/30/2026	
	OREGON	Retail Drug Outlet Registration	RP-0003866	4/6/2023	3/31/2026	
	PENNSYLVANIA	Non-Resident Pharmacy	NP000662	10/25/2016	8/31/2027	
	RHODE ISLAND	Pharmacy - Non-Resident	PHN12523	4/24/2024	9/30/2026	
	SOUTH CAROLINA	Non-Resident Pharmacy	22289	4/17/2024	6/30/2026	
	SOUTH DAKOTA	Non-Resident Pharmacy	400-2514	11/12/2024	6/30/2026	
	TENNESSEE	Pharmacy	6671	4/2/2019	9/30/2027	
	TEXAS	Class E Pharmacy	31993	4/20/2018	4/30/2026	
	UTAH	Pharmacy - Class D	13844018-1708	3/28/2024	9/30/2027	
	VERMONT	Non-Resident Pharmacy	036.0134941	1/22/2025	7/31/2027	
	VIRGINIA	Non-Resident Pharmacy	0214002124	9/21/2018	9/30/2025	Renewal pending receipt of inspection report
	WASHINGTON	Pharmacy Non-Resident	PHNR.FO.61691692	5/1/2025	5/31/2026	
	WEST VIRGINIA	Mail Order Pharmacy	MO0561211	6/26/2019	6/30/2027	
	WISCONSIN	Pharmacy	3530-43	3/10/2025	5/31/2026	
	WYOMING	Non-Resident Pharmacy	NR-52224	2/6/2023	6/30/2026	

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER, WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
BOARD OF PHARMACY

HAS PERMITTED

HOMECARE RX, INC DBA INFUCARE RX OF NJ
AMI D PATEL
45 Route 46, Unit 610
Pine Brook NJ 07058

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

06/09/2025 TO 06/30/2026
VALID

28RS00739900
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

ACTING DIRECTOR

New Jersey Office of the Attorney General
Division of Consumer Affairs
THIS IS TO CERTIFY THAT THE
BOARD OF PHARMACY
HAS PERMITTED
HOMECARE RX, INC DBA INFUCARE RX OF NJ
Pharmacy
06/09/2025 TO 06/30/2026
VALID
SIGNATURE
ACTING DIRECTOR
28RS00739900
License/Registration/Certificate #

PLEASE DETACH HERE

IF YOUR LICENSE/REGISTRATION/ CERTIFICATE ID CARD IS LOST PLEASE NOTIFY:
BOARD OF PHARMACY
PO BOX 45013
NEWARK, NJ 07101

PLEASE DETACH HERE

NEW JERSEY DIVISION OF
CONSUMER AFFAIRS

Elizabeth M. Harris
Acting Director



License Information

Accurate as of October 15, 2025 3:42 PM

Return to Search Results

Name: HOMECARE RX, INC DBA INFUCARE RX OF NJ

Address: Pine Brook,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00739900

License Status: Active

Status Change Reason: License Issuance

Issue Date: 4/15/2015

Expiration Date: 6/30/2026

Board Action: No

Prerequisites

Supervisor Information

Prereq Type: Prerequisite
Licensee: HOMECARE RX, INC DBA INFUCARE RX OF NJ **License No:** D10573100 **License Type:** CDS Pharmacy **License Status:** Active
Relationship: **Association Date:** **Expiration Date:** **Date Established:** 4/16/2015

Supervisor Information

Prereq Type: Prerequisite User
Licensee: Patel, Ami D **License No:** 28RI03544600 **License Type:** Pharmacist **License Status:** Active
Relationship: **Association Date:** 12/7/2015 **Expiration Date:** **Date Established:** 12/10/2015

Documents

No Public Documents

Copyright © 2017 State of New Jersey.

NEW JERSEY DIVISION OF
CONSUMER AFFAIRS

Elizabeth M. Harris
Acting Director



License Information

Accurate as of October 15, 2025 3:43 PM

Return to Search Results

Name: HOMECARE RX, INC DBA INFUCARE RX OF NJ

Address:
45 Route 46, Unit 610
Pine Brook NJ 07058

Profession/License Type: CDS,CDS Pharmacy

License No: D10573100

License Status: Active

Status Change Reason: License Issuance

Last Status Change Date: 4/16/2015

Issue Date: 4/16/2015

Expiration Date: 10/31/2026

Drug Schedule 1: **Drug Schedule 2:** Yes
Drug Schedule 4: Yes **Drug Schedule 5:** Yes **Drug Schedule 3:** Yes

For more information, please contact the Drug Control Unit at (973) 504-6351

Restrictions to Main License Status Main Lic#:

Prerequisite Information

Prereq Type: Prerequisite User
Licensee: HOMECARE RX, INC DBA INFUCARE RX OF NJ **License No:** 28RS00739900 **License Type:** Pharmacy **License Status:** Active
Relationship: **Association Date:** **Expiration Date:** **Date Established:** 4/16/2015

Documents

No Public Documents

Copyright © 2017 State of New Jersey

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FH5185738	10-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-01-2023

HOMECARE RX INC.
DBA INFUCARE RX OF NJ
45 ROUTE 46, UNIT 610
PINE BROOK, NJ 070589390

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FH5185738	10-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-01-2023

HOMECARE RX INC.
DBA INFUCARE RX OF NJ
45 ROUTE 46, UNIT 610
PINE BROOK, NJ 070589390

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4GGG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH _____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FI3859963 ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Part 1: General Information

Pharmacy Name: INNOVARX INC

Physical Address: 100 CAMPUS DRIVE SUITE 103

City: MORGANVILLE State: NJ Zip: 07751

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 732-490-5216 Toll Free # (NAC 639.708, NRS 639.23286): 888-659-0335

Fax: 732-399-2771 Contact Email: LICENSING@INNOVARXUSA.COM

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): ERIC BURD

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24627

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: ERIC BURD	NV Pharmacist Registration #: 24627
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy relating to the pharmaceutical industry?
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

...y partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10...
...ublicly traded stock

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NJ

Parent Company (if any): _____

Corporation/Organization Name: INNOVARX INC

Mailing Address: 100 CAMPUS DRIVE SUITE 103

City: MORGANVILLE State: NJ Zip: 07751

Telephone: 732-490-5219 Email: LICENSING@INNOVARXUSA.COM

Contact Person Name: ERIC BURD

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____ SEC Registration Number _____ Stock Exchange Symbol

Mailing Address: _____ ...olders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____ Non-Publicly Traded Corporation or Company

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____ ...holders/shareholders of the corporation or member exceed four? NRS 639.231 ☐ Yes ☐ No

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility- MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PHARMACIST (title) for INNOVARX INC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

PHARMACIST (title) for INNOVARX INC (name
ERIC BURD in that capacity, I am authorized to speak on the Pharmacy's behalf.
Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted) 12/16/2025 Date

PHARMACIST (title) for INNOVARX INC (name
ERIC BURD in that capacity, I am authorized to speak on the Pharmacy's behalf.
Print Name of Authorized Person

12/16/2025
Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

Pharmacy Application

I, ERIC BURD hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST (title) for INNOVARX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature (title) for INNOVARX (name)

SUBSCRIBED AND SWORN TO

Before me, a notary public this 11th day of December, 2025

Notary Public

VYACHESLAV KHEYMAN
NOTARY PUBLIC-STATE OF NEW YORK
No. 01KH6218013
Qualified in Richmond County
My Commission Expires 02-22-2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ERIC BURD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

12/16/2025

Date

Board Use Only	Date Received: 1/5/26	Amount: —

InnovaRx Inc.

100 Campus Dr
Suite 103
Morganville, NJ 07751

Organizational Chart / List of Officers / Shareholders

Name	Title
Alexandra Nissengolts	President 100%

Alexandra Nissengolts
President

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
LONG FORM STANDING WITH OFFICERS AND DIRECTORS

INNOVARX INC
0451025180

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on September 20, 2023.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

ALEXANDRA NISSENGOLTS
100 CAMPUS DR.
SUITE 103
MORGANVILLE, NJ 07751

I further certify that as of the date of this certificate, the following were listed as officers/directors of this business.

OTHER	*ALEXANDRA NISSENGOLTS* *100 CAMPUS DR* *SUITE 103* *MORGANVILLE, NJ 07751*

Continued on next page...

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
LONG FORM STANDING WITH OFFICERS AND DIRECTORS

INNOVARX INC
0451025180



IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 7th day of June, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6154244375

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES

CERTIFICATE OF INC. (PROFIT)

INNOVARX INC
0451025180

The above-named DOMESTIC PROFIT CORPORATION was duly filed in accordance with New Jersey State Law on 09/20/2023 and was assigned identification number 0451025180. Following are the articles that constitute its original certificate.

1. **Name:**
   INNOVARX INC

2. **Registered Agent:**
   ALEXANDRA NISSENGOLTS

3. **Registered Office:**
   100 CAMPUS DR.
   SUITE 103
   MORGANVILLE, NEW JERSEY 07751

4. **Business Purpose:**
   PHARMACY

5. **Duration:**
   PERPETUAL

6. **Stock:**
   200

7. **Effective Date of this filing is:**
   09/20/2023

8. **First Board of Directors:**
   ALEXANDRA NISSENGOLTS
   100 CAMPUS DR
   SUITE 103
   MORGANVILLE, NEW JERSEY 07751

9. **Incorporators:**
   ALEXANDRA NISSENGOLTS
   100 CAMPUS DR.
   SUITE 103
   MORGANVILLE, NEW JERSEY 07751

10. **Main Business Address:**
    100 CAMPUS DR
    SUITE 103
    MORGANVILLE, NEW JERSEY 07751

Signatures:
ALEXANDRA NISSENGOLTS
INCORPORATOR

Continued on next page ...

NEW JERSEY DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES

CERTIFICATE OF INC. (PROFIT)

Con **INNOVARX INC** ...
0451025180

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal 20th day of September, 2023

Elizabeth Maher Muoio
State Treasurer

Certificate Number: 42205183529
Verify this certificate online at
https://www1.state.nj.us/TYTR_StandingCertUST/Verify/Certify

NEW JERSEY DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES

CERTIFICATE OF INC. (PROFIT)

INNOVARX INC
0451025180

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal 20th day of September, 2023

Elizabeth Maher Muoio
State Treasurer

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler INNOVARX INC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 100 CAMPUS DRIVE SUITE 103

City MORGANVILLE State NJ Zip 07751

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 732-490-5216 Website _____

Licensing Company Email LICENSING@INNOVARXUSA.COM

Section 2: Personal Information

First ERIC Middle NORMAN Last BURD

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] pplication Sex ☑ M ☐ F ☐ X

Mailing Addr[redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Emai[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
CLIFFISIDE PARK HS			09/2002-05-2006
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
HIGH SCHOOL GRADUATION			

School Name			From - To (MM/YY – MM/YY)
NORTHEASTERN UNIVERSITY			09/2006-05-2010
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
BACH IN BIOLOGY			

School Name			From - To (MM/YY – MM/YY)
UNIVERSIDAD DE IBEROAMERICA			01/11-05/15
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
PHARMD			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/23-PRESENT	[redacted]			
06/17-09/23				

all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper space is needed.)

HARRIS AVE	STATEN ISLAND	NY	10309
JNDLER AND CT	MARLBORO	NJ	3417

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in [illegible] (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution [illegible] related to prescription drugs. Beginning with the most current, list your hours of employment [illegible]

Business Name			From - To (MM/YY – MM/YY)
INNOVARX			09/23-PRESENT
Business Address	**City**	**State**	**Zip**
100 CAMPUS DRIVE SUITE 103	MORGANVILLE	NJ	07751
Phone	**Title**		**Number of Employed Hours**
732-490-5216	PHARMACIST		40
Description of Duties			
STAFF PHARMACIST			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			
[illegible] designated representative must provide proof that he or she has been employed for at least 6,000 hours in [illegible]			

Business Name			From - To (MM/YY – MM/YY)
[illegible] the [illegible] your			
Business Address	**City**	**State**	**Zip**
			NJ
Phone	**Title**		**Number of Employed Hours**
[illegible] DRIVE SUITE 103			
Description of Duties			
PHARMACIST			40

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			
[illegible] DUTIES			

Continue on next page if additional space is needed.

From - To (MM/YY

Section 8: Arrests, Detentions, Litigations, Arbitrations		
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, ERIC BURD (print accepted), certify that as the designated representative for

INNOVARX INC

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. EB I am at least 21 years of age;
3. EB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. EB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. EB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. EB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. EB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

, certify that as the designated representative for

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

I am at least 21 years of age;

I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;

I will be employed full-time in a managerial level position with the pharmacy or wholesaler;

I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and

I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

ERIC BURD

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/16/2025

Date

Original Signature (electronic copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ERIC BURD

Print Name (First, Last)

12/16/2025

Original Signature (electronic, copies or stamps not accepted) Date

---

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Please have this section completed in the presence of a Notary Public.

State of New York ss. County of Richmond

I, Eric Burd, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/19/25

Date

Subscribed and Sworn to before me this 19 day of December 2025.

Please have this section completed in the presence of a Notary Public.

Notary Public Signature

VYACHESLAV KHEYMAN
NOTARY PUBLIC-STATE OF NEW YORK
No. 01KH6218013
Qualified in Richmond County
My Commission Expires 02-22-2026

(Seal)

ss. County of

being duly sworn, depose and say I have read the

thereof that the statements contained herein are true and correct

the information requested that I executed this statement with the

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site INNOVARX INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 100 CAMPUS DRIVE SUITE 103

City MORGANVILLE State NJ Zip 07751

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 732-490-5216 Website _____

Licensing Company Email LICENSING@INNOVARXUSA.COM

Section 2: Personal Information

First ALEXANDRA Middle _____ Last NISSENGOLTS

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)

1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)

2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
MIDWOOD HIGH SCHOOL		08/06-05/10	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
HS DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
TOURO COLLGE		09/10-04/14	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/23-PRESENT	[redacted]			
03/15-09/23				

If ... dence you have had for the last 10 years beginning with ... most current. (Use a separate piece of paper ... needed.)

	City	State	
	SI AND	NYAN	10

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner or in any related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)
INNOVARX INC		09/23-PRESENT

Business Address	City	State	Zip
100 CAMPUS DRIVE	MORGANVILLE	NJ	07751

Phone	Title
732-490-5216	OWNER

Description of Duties
DUTIES OUTSIDE OF PHARMCY PRACTICE - HR/PAYROLL/DAY TO DAY DUTIES OF BUSINESS OWNER

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a pending manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ALEXANDRA NISSENGOLTS

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/16/2025

Date

Please have this section completed in the presence of a Notary Public.

State of [illegible] ss. County of [illegible]

I, Alexandra Nissengoltz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/19/25

Date

Subscribed and Sworn to before me this 19 day of December 2025

Notary Public Signature

VYACHESLAV KHEYMAN
NOTARY PUBLIC-STATE OF NEW YORK
No. 01KH6218013
Qualified in Richmond County
My Commission Expires 02-22-2026
(Seal)

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: 11/13/2025
File number: 8-7257-25-1723

Board of Pharmacy Inspection Report

This section is required: Page 1 of 3

InnovaRx Inc
Pharmacy trade name

Corporation name (if not the same)

Owner (as identified on the occasion of this inspection)
100 Campus Drive, Suite 103
Street address
Morganville, New Jersey 07751
City State ZIP code

(Paste pharmacy label here)

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

Vyacheslav Kheyman | 28RS00799600 | 06/30/2026
Name of permit holder | Certificate number | Expiration date

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

D12686700 | 10/31/2026
Certificate number | Expiration date

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

[redacted]Rx Inc | 11/30/2026
Certificate number | Expiration date

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): Vyacheslav Kheyman
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☑ Yes ☐ No)

28RI04438600 | 04/30/2027 | 40
Permit number | Expiration date | Hours worked per week

1. Is the registered pharmacist-in-charge's current renewal on display? ☑ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
[Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☑ Yes ☐ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
Vyacheslav Kheyman	RPIC	28RI04438600	☑ Yes ☐ No	40
Jacob Claudio	Pharmacy Technician	28RW04391600	☑ Yes ☐ No	40
Roxanne Brochado	Pharmacy Technician	28RW02110800	☑ Yes ☐ No	40
Boris Nissengolts	Pharmacy Technician	28RW05227300	☑ Yes ☐ No	40
Denys Goorvky	Pharmacy Technician	28RW05054700	☑ Yes ☐ No	40

New Jersey Office of the Attorney General

Division of Consumer Affairs

Board of Pharmacy

Inventory Quality Assurance Examination

This section is required: Page 2 of 3

Cheslav Kheyman — RPIC 28RP04438600 — Yes ☐ No

Jacob Claudio — Pharmacy Technician 28RW04391600 — Yes ☐ No

Roxanne Brochado — Pharmacy Technician 28RW02110800 — Yes ☐ No

Boris Nissengolts — Pharmacy Technician 28RW05227500 — Yes

Pharmacy: InnovaRx Inc Date: 11/13/2025

Pharmacy Technician 28RW05054700 — Yes ☐ No

Street Address: 100 Campus Drive, Suite 103

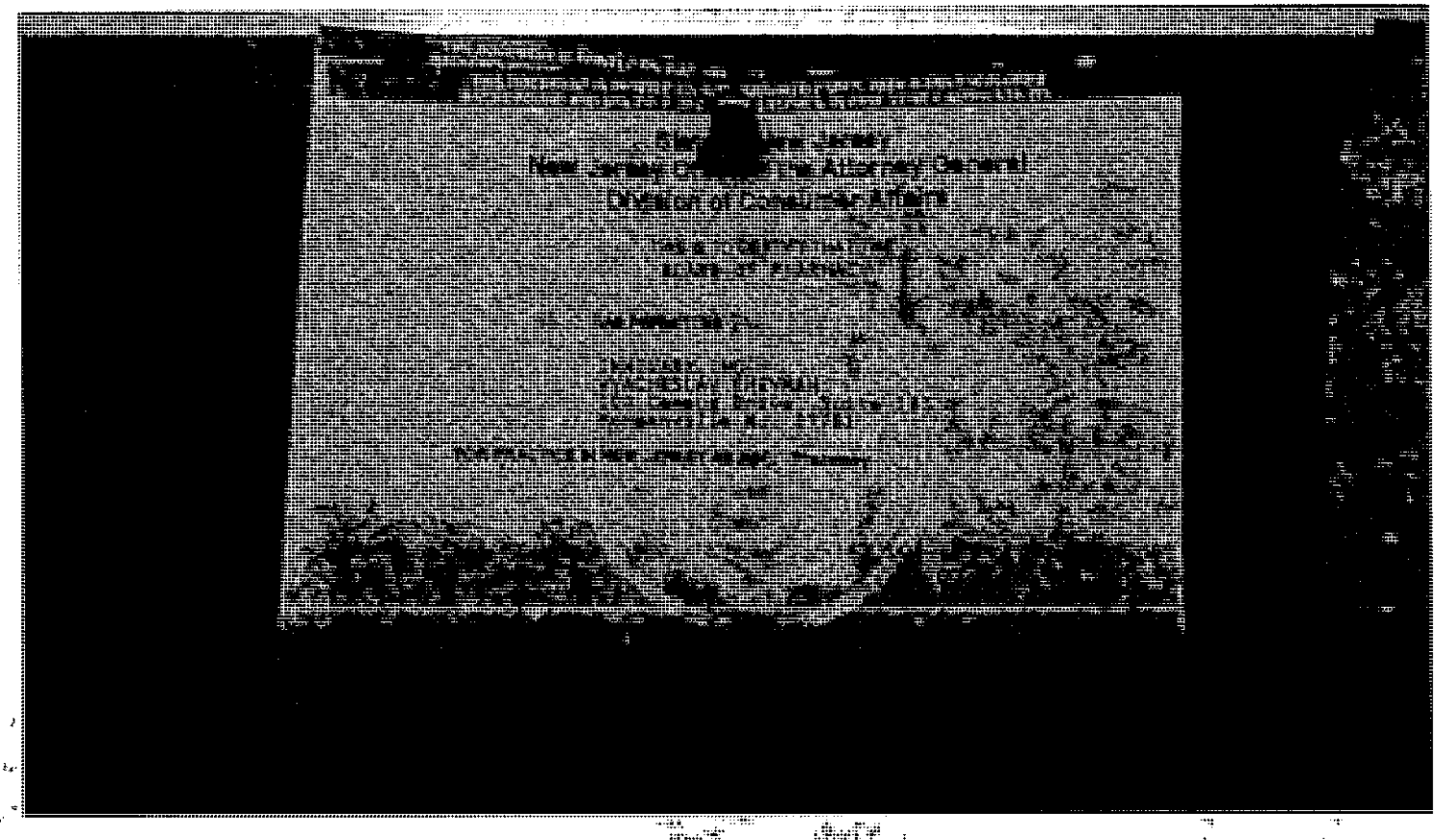
City, State, ZIP: Morganville, New Jersey 07751 Jennifer M. Geisler, RPh

Inspector

The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

Initials of Registered Pharmacist	Quantity or Commercial Package Size	Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Deficiencies [13:39–7.18] [13:39-6.2(f)7] Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												



State of New Jersey

DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
PO BOX 45013
NEWARK, NJ 07101

Philip D. Murphy
Governor

TAHESHA L. WAY
Lt. Governor

Matthew J. Platkin
Attorney General

ELIZABETH M. HARRIS
Acting Director

October 15, 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by INNOVARX INC to forward a letter of good standing regarding the Pharmacy's registration to practice in the State of New Jersey.

A review of the Board's files indicates that INNOVARX INC was issued a New Jersey registration 28RS00799600 on or about 02/16/2024 and is currently Active and in good standing with an expiration date of 06/30/2026. A review of the Board's files further indicates that no public disciplinary action has been taken against this Pharmacy.

Very truly yours,

Anthony Rubinaccio, RPh
Executive Director

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by INNOVARX INC to forward a letter of good standing regarding the Pharmacy's registration to practice in the State of New Jersey.

A review of the Board's files indicates that INNOVARX INC was issued a New Jersey registration 28RS00799600 on or about 02/16/2024 and is currently Active and in good standing with an expiration date of 06/30/2026. A review of the Board's files further indicates that no public disciplinary action has been taken against this Pharmacy.

Very truly yours,

Executive Director

124 HALSEY STREET, 6th FLOOR, NEWARK, NJ 07102 · TELEPHONE: 973-504-6450 FAX: 973-504-6326
New Jersey is an Equal Opportunity Employer · Printed on Recycled Paper and Recyclable

Phillip D. Murphy
Governor

TAHESHA L. WAY
Lt. Governor

State of New Jersey

DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
PO BOX 45013
NEWARK, NJ 07101

Matthew J. Platkin
Attorney General

ELIZABETH M. HARRIS
Acting Director

October 15, 2025

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by ERIC N BURD to forward a letter of good standing regarding the Pharmacist's registration to practice in the State of New Jersey.

A review of the Board's files indicates that ERIC N BURD was issued a New Jersey registration 28RI03905100 on or about 10/30/2017 and is currently Active and in good standing with an expiration date of 04/30/2027. A review of the Board's files further indicates that no public disciplinary action has been taken against this Pharmacist.

Very truly yours,

Anthony Rubinaccio, RPh
Executive Director

Phillip D. Murphy
Governor

TAHESHA L. WAY
Lt. Governor

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
PO BOX 45013
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October 15, 2025

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by ERIC N BURD to forward a letter of good standing regarding the Pharmacist's registration to practice in the State of New Jersey.

A review of the Board's files indicates that ERIC N BURD was issued a New Jersey registration 28RI03905100 on or about 10/30/2017 and is currently Active and in good standing with an expiration date of 04/30/2027. A review of the Board's files further indicates that no public disciplinary action has been taken against this Pharmacist.

Very truly yours,

Anthony Rubinaccio, RPh
Executive Director

124 HALSEY STREET, 6th FLOOR, NEWARK, NJ 07102 · TELEPHONE: 973-504-6450 FAX: 973-504-6326
New Jersey is an Equal Opportunity Employer · Printed on Recycled Paper and Recyclable

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FI3859963	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY-COLLECTOR	02-28-2024

INNOVARX INC.
100 CAMPUS DR STE 103
MORGANVILLE, NJ 077511253

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FI3859963	11-30-2026	$888

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2,2N,3, 3N,4,5	RETAIL PHARMACY-COLLECTOR	02-28-2024

INNOVARX INC.
100 CAMPUS DR STE 103
MORGANVILLE, NJ 077511253

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223 (9/2016)

11-30-2026 $888

02-28-2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Innavax Inc

Address: 100 Campus Drive #103

City: Marlborough State: NJ Zip: 07751

I hereby authorize the NJ BOP to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
28RS00799600	Active	2/16/24	6/30/26

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☒ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☒ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☒ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☒ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☒ Yes ☐ No

Signature of State Official	Title	State	Date
[signature]	ASR	NJ	12/17/25

BOARD OF PHARMACY STATE OF NEW JERSEY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Eric Bud

Address: 98 Harris Ln

City: Staten Island State: NY Zip: 10309

I hereby authorize the NJ BOP to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
28RI0305100	Active	10/30/17	4/30/27

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☒ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☒ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☒ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☒ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☒ Yes ☐ No

Signature of State Official	Title	State	Date	S
[signature]	ASR	NJ	12/17/25	

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NEC

STATE OF NEW JERSEY BOARD OF PHARMACY

4HHH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☑ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: F9634863
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: 237 Cahaba Valley, LLC dba Magic City Pharmacy

Physical Address: 237 Cahaba Valley Parkway

City: Pelham State: AL Zip: 35124

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-245-4390 Toll Free # (NAC 639.708, NRS 639.23286): 888-245-4390

Fax: 833-307-2648 Contact Email: licensingmcp@biote.com

Website: www.magiccity503a.com

Nevada Business License # (if applicable) NV20253443478

Supervising/Managing Pharmacist Name (NRS 639.220): Brittney Nixon

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Cindy Mitman	NV Pharmacist Registration #: 19891
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Alabama

Parent Company (if any): BioTE Medical, LLC

Corporation/Organization Name: BioTE Medical, LLC

Mailing Address: 1875 W. Walnut Hill Lane Ste. 100

City: Irving State: TX Zip: 75038

Telephone: 844-604-1246 Email: licensingmcp@biote.com

Contact Person Name: Robert Peterson

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO (title) for 237 Cahaba Valley, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Robert Peterson

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1-7-2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Robert Peterson hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO (title) for 237 Cahaba Valley, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 7 day of January, 20 26

Notary Public

KENDAL MCNEELY
Notary Public, State of Texas
Comm. Expires 04-22-2028
Notary ID 132447949

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Peterson

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

1-7-2026

Date

Board Use Only	Date Received: 1/26/26	Amount: 500.00/ V# 2381

Organizational Chart

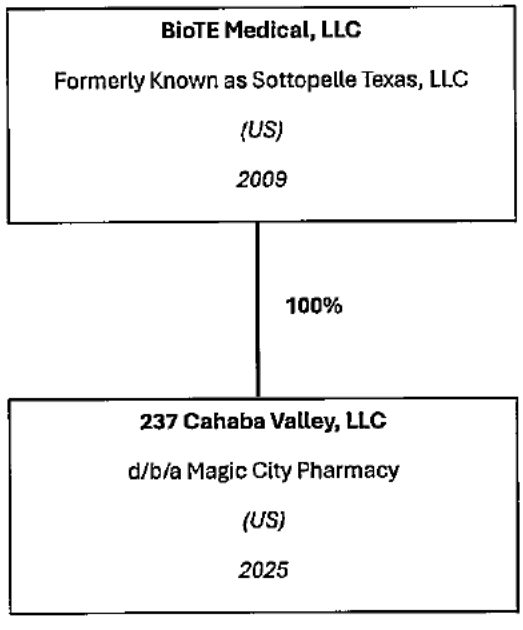
237 Cahaba Valley, LLC

d/b/a Magic City Pharmacy

Officers:
Bret Christensen CEO
[redacted]

[redacted]

Robert Peterson CFO
[redacted]



Wes Allen
Secretary of State

P.O. Box 5616
Montgomery, AL 36103-5616

STATE OF ALABAMA

I, Wes Allen, Secretary of State of Alabama, having custody of the Great and Principal Seal of said State, do hereby certify that

the entity records on file in this office disclose that 237 Cahaba Valley, LLC was formed in Alabama on August 20, 2025. The Alabama Entity Identification number for this entity is 001-206-633. I further certify that the records do not disclose that said entity has been dissolved, cancelled or terminated.

In Testimony Whereof, I have hereunto set my hand and affixed the Great Seal of the State, at the Capitol, in the city of Montgomery, on this day.

09/19/2025

Date

Wes Allen **Secretary of State**

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler 237 Cahaba Valley, LLC dba Magic City Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 237 Cahaba Valley Parkway

City Pelham State AL Zip 35124

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-245-4390 Website www.magiccity503a.com

Licensing Company Email licensingmcp@biote.com

Section 2: Personal Information

First Brittney Middle _____ Last Nixon

Alias(es, nicknames, name changes, etc.) N

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: McWhorter School of Pharmacy - Samford University			From - To (MM/YY – MM/YY): 08/13 05/17	
Address: 2100 Lakeshore Dr	City: Birmingham		State: AL	Zip: 35229
Diploma/Degree obtained, if any: Pharm D				
School Name: Samford University			From - To (MM/YY – MM/YY): 08/13 - 05/15	
Address: 800 Lakeshore Dr	City: Birmingham		State: AL	Zip: 35229
Diploma/Degree obtained, if any: Bachelor of Health Sciences				
School Name: University of Alabama at Birmingham			From - To (MM/YY – MM/YY): 08/12 - 05/13	
Address: 1720 Second Ave S	City: Birmingham		State: AL	Zip: 35233
Diploma/Degree obtained, if any:				
School Name: Huntingdon College			From - To (MM/YY – MM/YY): 08/09 - 05/12	
Address: 1500 E Fairview Ave	City: Montgomery		State: AL	Zip: 36106
Diploma/Degree obtained, if any:				
School Name: Cornerstone Christian School			From - To (MM/YY – MM/YY): 08/05 - 05/09	
Address: 24975 SR-25	City: Columbiana		State: AL	Zip: 35051
Diploma/Degree obtained, if any:				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/22 - present	[redacted]			
10/21 - 10/22				
05/17 - 10/21				
01/96 - 05/17				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Magic City Pharmacy			From - To (MM/YY – MM/YY): 10/25 - present
Business Address: 237 Canaba Valley Pkwy	City: Pelham	State: AL	Zip: 35124
Phone: 888-245-4390	Title: Pharmacist in Charge	Number of Employed Hours: 440	
Description of Duties: ~~devot~~ develop policies and procedures, daily pharmacy operations, staff utilization and management, record keeping			

Business Name: Davis Drugs			From - To (MM/YY – MM/YY): 01/23 - 10/25
Business Address: 111 S mainstreet	City: Columbiana	State: AL	Zip: 35051
Phone: (205) 669-6713	Title: Pharmacy manager	Number of Employed Hours: 5,400	
Description of Duties: develop policies and procedures, daily pharmacy operations, staff utilization and management, record keeping			

Business Name: CVS Pharmacy			From - To (MM/YY – MM/YY): 07/22 - 01/23
Business Address: 3303 Clairmont Ave	City: Birmingham	State: AL	Zip: 35222
Phone: (205) 322-3055	Title: Pharmacy manager / PIC	Number of Employed Hours: 1,040	
Description of Duties: daily pharmacy operations, staff utillization and management, record keeping			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:	Number of Employed Hours:	
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Brittney Nixon, **certify that as the designated representative for**

237 Cahaba Valley, LLC dba Magic City Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BN I am at least 21 years of age;
3. BN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brittney Nixon
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/18/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brittney Nixon

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/18/25

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Shelby

I, Brittney Nixon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/18/25

Date

Subscribed and Sworn to before me this 18th day of December, 2025

Notary Public Signature

ELIZABETH LEWIS TITTLE
NOTARY PUBLIC
State of Alabama - State at Large
My Commission Expires Jun. 23, 2029

(Seal)

Name
237 Cahaba Valley, LLC - Follow Up

DBA

Address
237 Cahaba Valley Parkway
Pelham, AL 35124
Shelby

Permit #
115475

CS #
- ()

Compounding #

Pharmacist In Charge
Brittney Calma Nixon

DEA #:

DEA Expiration:

Inspection Date
11/25/2025

Inspection User
Delk, Mark

Assigned To

Status
Follow up

Inspected new permit location at 237 CAHABA VALLEY PKWY. WATER LINES RUN, FRONT SECURITY DOOR NOT IN PLACE, REVIEWED COUNTER TOP SIZE. ADVISED RPH NIXON 20119, to notify me when door and counter tops in place. No medication is to be dispensed prior to final inspection and notification.

	Answer	Question
1)	Yes	Pharmacy space and layout 16 sq. ft. counter space; 24 sq. ft. if 2 or more pharmacists; total pharmacy space minimum 240 sq. ft. (34-23-71)
2)	Not Applicable	Reference Books or online data: Facts and Comparisons. (680-x-2-.04)
3)	Not Applicable	All required licenses and permits are displayed prominently. (34-23-70(b))
4)	Not Applicable	Private consultation area available. (680-X-2-.27)
5)	Not Applicable	Is the method used to collect patient signatures to approve or refuse pharmacist counseling HIPAA compliant? (Signatures should not be visible to other customers)
6)	Not Applicable	Pharmacy Staff makes verbal offer to counsel on each new prescription. (680-x-2-.21)
7)	Yes	Access to pharmacy (keys or code) with pharmacist only. (680-X-2-.11)
8)	Not Applicable	Designated Key Holder. (List Name) (Approval Form must be posted in pharmacy) (680-X-2-.11)
9)	Not Applicable	Refrigerator is clean, temperature between 2 - 8 degrees C, or 36-46 degrees F.

Comments: Advised to install refrigerator temperature monitor.

	Answer	Question
10)	Not Applicable	Only drug related products stored in refrigerator.
11)	Not Applicable	Prescription area is clean and orderly. Minimal chance to confuse orders.
12)	Not Applicable	Drugs in date. (34-23-9)
13)	Yes	Drugs purchased from reputable sources. (34-23-32-1)

Comments: MCKESSON

14)	Not Applicable	Do you provide prescriptions to patients in a Skilled Nursing Facility (SNF) and/or Intermediate Care Facility (ICF)?
15)	Not Applicable	Pharmacy technicians: supervised, registered, have name tag. (34-23-131)
16)	Not Applicable	Pharmacist:technician ratio of 1:2, 1:3 if one tech is certified, 1:4 if two technicians are certified. (680-x-2-.14)
17)	Not Applicable	Pharmacy technician manual: may use www.albop.com. (680-X-2-.14(5))
18)	Not Applicable	Technicians have been trained in all assigned tasks. (680-X-2-.14(5))
19)	Not Applicable	Are technicians prevented from processing/receiving prescriptions before a pharmacist arrives or after the pharmacist leaves?
20)	Not Applicable	Does a pharmacist verify all work performed by technicians and document this verification?
21)	Not Applicable	Pharmacy connected to NPLEX if selling ephedrine/pseudoephedrine products. (Those selling by prescription only, do not have to submit to database) (20-2-190)
22)	Not Applicable	Pharmacy is reporting to PDMP. (Pharmacies should be uploading daily) (Should be uploading a zero balance even if no CS filled) (20-2-213)
23)	Not Applicable	Controlled Substance Inventory. (Date of Last Inventory) (680-X-3-.08)

Comments: Advised RPH NIXON TO PERFORM OPENING CS INVENTORY AND JANUARY 15th.

24)	Not Applicable	Refills limited to prescriber's orders.
25)	Not Applicable	Recordkeeping of prescriptions. (initials, number, date, label, compounding notes)
26)	Not Applicable	All controlled substance prescriptions shall bear full name and address of the patient along with date, drug strength, dosage form, quantity, directions for use, and name, address and registration number of practitioner.
27)	Not Applicable	Pharmacy takes back non-controlled medication from patients for destruction.

	Answer	Question
28)	Not Applicable	Pharmacy takes back controlled medication from patients for destruction.
29)	Not Applicable	Quarantined all out-dated medications (both prescription and OTC)? Note: This includes compounding supplies and items in the refrigerator.
30)	Not Applicable	Have a separate clean area for any compounding. (only compounding equipment, orderly, clean)
31)	Not Applicable	Compounding area has washable counter, floors, ceiling, shelves.
32)	Not Applicable	Sink with potable hot and cold water, sink clean, available to hand washing before compounding.
33)	Not Applicable	Prescription Balance/scale and Weights" Technical Equipment commensurate with level of practice.
34)	Not Applicable	Purified water used for compounding or reconstitution.
35)	Not Applicable	Last time calibrated balance or scale Date? (All answers go in comments)
36)	Not Applicable	Prepares a compounding record with each compound which includes amount of each ingredient, lot number and expiration date.
37)	Not Applicable	Master Formula and compounding instructions available for commonly used formulas.
38)	Not Applicable	Compounding of hazardous drugs follows USP 800.
39)	Not Applicable	Any staff who compound hazardous drugs have been trained and have signed an informed consent.
40)	Not Applicable	Are you able to identify brand name, or generic name and manufacturer; strength; lot number; expiration date; or an internal control number which references the manufacturer and lot number used for medications placed into all cells in automated dispensing machines?
41)	Not Applicable	Does pharmacist verify technician filling of automated dispensing machines?

Full Name:

RPH NIXON 20119.

Alabama State Board of Pharmacy

2026

This is to certify:

237 Cahaba Valley, LLC
DBA Magic City Pharmacy
237 Cahaba Valley Parkway
Pelham, AL 35124

Permit Number:

115475

Is Duly Licensed as a:

Community Pharmacy

Specialty Services:

Non-Sterile Compounding

Supervising Pharmacist

Brittney Calma Nixon
20119

IN COMFORMITY WITH THE PROVISIONS OF ACT #205, GENERAL ACTS OF ALABAMA, 1966 SPECIAL SESSION, AND RULES AND REGULATIONS OF THE BOARD. THIS CERTIFICATE MUST BE CONSPICIOUSLY DISPLAYED AND EXPIRE ON THE LAST DAY OF

December 2026

THIS IS YOUR RECEIPT FOR FEE PAID AS REQUIRED BY LAW
THIS PERMIT IS NOT TRANSFERRABLE

EXECUTIVE SECRETARY

Alabama State Board of Pharmacy

2026

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE

Controlled Substance Number:

CS115475

Business Activity:

Community Pharmacy

Schedules:

AL, II, III, IV, V

The Controlled Substance Act of 1971 reads in part as follows:
Section 304 (Revocation and Suspension of the Registration.)

(a) A registration under Section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Certifying Boards upon a finding that the registrant:

(1) Has furnished false or fraudulent material information in any application filed under this Act,

(2) Has been convicted of a felony under any State or Federal law relating to any controlled substance or

(3) Has had his Federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances

(4) Has violated the provisions Act 205 (al-a32) Code of Alabama 1940 (Recomp. 1958)

Date Issued: 12/10/2025

Expiration Date: 12/31/2026

237 Cahaba Valley, LLC
DBA Magic City Pharmacy
237 Cahaba Valley Parkway
Pelham, AL 35124

CERTIFICATE MUST BE PROMINENTLY DISPLAYED AT ALL TIMES

ALABAMA STATE BOARD OF PHARMACY

111 Village Street
Birmingham, AL 35242

Permit Verification

Name: 237 Cahaba Valley, LLC

Pharmacy Number: 115475

Permit Type: Pharmacy

Permit Status: Active

Date Issued: 11/25/2025

Expiration Date: 12/31/2026

Disciplinary Action: No Discipline

Date Prepared: December 19, 2025

Jon Linna, R.Ph.
Executive Secretary

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
F96348634	04-30-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-17-2025

237 CAHABA VALLEY, LLC
DBA MAGIC CITY PHARMACY
237 CAHABA VALLEY PKWY
PELHAM, AL 351241146

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
F96348634	04-30-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-17-2025

237 CAHABA VALLEY, LLC
DBA MAGIC CITY PHARMACY
237 CAHABA VALLEY PKWY
PELHAM, AL 351241146

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Y

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	☐ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH PH03575		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Optime Care Inc.

Physical Address: 4060 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 314-731-6900 Toll Free # (NAC 639.708, NRS 639.23286): 888-287-2017

Fax: 888-868-3147 Contact Email: licensing@optimecare.com

Website: www.optimecare.com

Nevada Business License # (if applicable) PH03575

Supervising/Managing Pharmacist Name (NRS 639.220): Sergio Barranco-Medina

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21515

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Sergio Barranco-Medina	NV Pharmacist Registration #: 21515
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Innovative Specialty Solutions, LLC

Corporation/Organization Name: Optime Care Inc.

Mailing Address: 4060 Wedgeway Ct

City: Earth City State: MO Zip: 63045

Telephone: 888-287-2017 Email: licensing@optimecare.com

Contact Person Name: Jennifer Keyser

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Optime Care Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Bill Oldham

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/2/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Bill Oldham hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Optime Care Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 2nd day of September, 20 25

Notary Public

Commonwealth of Pennsylvania - Notary Seal
JENNIFER KEYSER - Notary Public
Chester County
My Commission Expires May 30, 2029
Commission Number 1241109

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bill Oldham

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9-2-2025

Date

Board Use Only	Date Received: 12/1/25	Amount: $500 CK 6015

Summary of Disciplinary Actions Taken Against Optime Care, Inc.

1. Settlement Agreement executed by and between Optime Care Inc. ("Optime") and the Hawaii Department of Commerce and Consumer Affairs – Board of Pharmacy (the "HI Board"), eFiled by the HI Board on February 14, 2023 and delivered to Optime on February 22, 2023 (the "Agreement"). In settlement of the allegations noted in the Agreement, a Settlement Agreement was offered by the HI BOP with a fine imposed in the amount of $2,500. The Agreement was accepted by both parties, the fine was paid and the matter is closed.

The disciplinary action was taken against Optime by the HI Board due to Optime Care's failure to report a Consent Order executed by and between Optime and the Michigan Department of Licensing and Regulatory Affairs ("MI LARA") on its Hawaii pharmacy license renewal applications submitted prior to the Change of Ownership that occurred in December of 2021. The omission on the renewal applications was not intentional on the part of Optime. Through conversations with the MI LARA and Optime's outside legal counsel at the time, it was the understanding of the Optime management personnel that the Consent Order was not a 'reportable' matter. The interpretation of the Michigan matter under Optime's new ownership was that the action should be disclosed to assure complete transparency and, as such, the Consent Order was reported on the December 2021 change of ownership applications filed with all applicable pharmacy boards, including the Rhode Island Board, and all subsequent renewal applications.

The Hawaii Board of Pharmacy Settlement Agreement was reported to the Maine Board of Pharmacy via written communication dated February 17, 2023.

2. Consent Order executed by and between Optime Care Inc. ("Optime") and the Alabama Board of Pharmacy (the "AL Board"), received on May 5, 2023 with an effective date of March 15, 2023 (the "AL Order"). In settlement of Case No. 22-L-0021, a Consent Order was executed and a fine in the amount of $5,000 was imposed. The fine was paid and the matter is closed.

The disciplinary action was taken against Optime by the AL Board for the following violations:

1. Optime dispensing medications into the State of Michigan prior to issuance of the required Michigan pharmacy license. Optime was disciplined by the Michigan Board of Pharmacy for this oversight.

2. Optime's omission in not disclosing the Michigan action on the Louisiana renewal application in 2020. The omission on the renewal application was not intentional on the part of Optime. Through conversations with the Michigan Board of Pharmacy and Optime's outside legal counsel at the time, it was the understanding of the Optime management personnel that the Consent Order was not a 'reportable' matter. However, the interpretation of the Michigan matter under Optime's new ownership was that the action should be disclosed to assure complete transparency and, as such, the Consent Order has been reported on all subsequent pharmacy licensure applications for all applicable pharmacy boards.

The Alabama Board of Pharmacy Consent Order was reported to the Maine Board of Pharmacy via written communication dated May 9, 2023.

3. Imposition of Civil Fine and Order executed by and between Optime Care Inc. ("Optime") and the Alaska Division of Corporations, Business and Professional Licensing (the "AK Board"), received on May 13, 2024 with an effective date of April 11, 2024 (the "AK Order"). In settlement of a complaint filed by the Alaska Board of Pharmacy, Case No.: 2023-000283 22-L-0021, an Imposition of Civil Fine and Order was executed and a fine in the amount of $200 was imposed. The fine was paid and the matter is closed.

The disciplinary action was taken against Optime by the AK Board because Optime appointed a new Pharmacist-in-Charge in January of 2023. The AK Board was apprised of the change and the required Change of Pharmacist-in-Charge form was submitted; however, the notification was received outside of the required timeframe for notification of a new Pharmacist-in-Charge. The AK Board considered this to be a technical violation of the Alaska professional licensing statutes and regulations.

The Alaska Board of Pharmacy Imposition of Fine and Order was reported to the Maine Board of Pharmacy via written communication dated May 25, 2024.

LARA/HRD-021 (11/17)

Michigan Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing – Enforcement Division
P.O. Box 30670
Lansing, MI 48909
www.michigan.gov/healthlicense Department Due Date: 3/11/19
15/01/19

NOTICE OF LICENSURE/REGISTRATION SANCTION

Reprimand, Restitution, Fine, Probation, Limitation

Authority: 1978 P.A. 368, as amended

This completed form serves as notification, to you, that the licensee/registrant named below has had his or her professional license/registration sanctioned for violating one or more provisions of the Michigan Public Health Code. This licensee/registrant is NOT prohibited from practicing his or her profession as long as such practice is in accordance with the sanction(s) set forth below. **This notification is required by law.**

TYPE OR PRINT IN INK ONLY

First Name	Middle Name	Last Name
Donovan	James	Quill

Business Address (Enter street address, **NOT a P.O. Box**): 4060 Wedgeway Ct

City	State	Zip Code	Telephone Number w/Area Code
Earth City	MO	63045	888-287-2017

Type of License/Registration (Profession)	Michigan License/Registration Number
Pharmacy	5301011393

Type(s) of Sanction(s):

- ☐ REPRIMAND
- ☒ FINE IN THE AMOUNT OF $ 5,000.00 TO BE PAID BY _____ (Date)
- ☐ RESTITUTION IN THE AMOUNT OF $ _____ TO BE PAID BY _____ (Date)
- ☐ LIMITATION* UNTIL _____ (Date)
- ☐ PROBATION* UNTIL _____ (Date)

*Please describe the terms of limitation and/or probation below. Attach additional sheets if necessary.

Effective Date of Sanction	Date Transmitted to Employer(s)
2/15/2019	2/15/2019
Date Sent to Hospital(s)	Date Sent to the Department
	2/26/2019
Signature of Sanctioned Licensee/Registrant	Date Signed
[signature]	2/26/2019

(OVER)

AFFIDAVIT

I, being the undersigned, do hereby state that:

1. I have completed and reviewed the Notice of Licensure/Registration Sanction (hereafter "Notice") on the opposite side of this Affidavit for correctness.

2. I understand that the address I provided on the Notice may not be the address of record on file with the Department of Licensing and Regulatory Affairs. I further understand that all correspondence will be sent to the address of record, that this Notice does **NOT** serve as notification of a change of address of record, and that it is my responsibility to file a change of address with the Department's Licensing Section.

☐ 3. I have personally signed the completed Notice AND transmitted a copy of the signed, completed Notice to each hospital in which I am admitted to practice AND my employer within ten days after the date of the Order imposing the sanction(s);

Please check the box for either #3 or #4

OR

☐ 4. I am not employed and do not meet the criteria set forth in Sections 16241(6) and 16241(7) of the Public Health Code, as set forth in the above item #4.

I swear or affirm that the contents of this Affidavit are true and to the best of my knowledge. I understand that falsification of this affidavit may result in the imposition of further administrative sanctions against my license(s) or registration.

Donovan J Quill

Print or Type Name:

Signature of Affiant:

Date Signed: 2/26/2019

County of Lincoln)

Signed and sworn to before me this 26th day of February, 2019.

Notary Public

CINDY L HOHN
Notary Public - Notary Seal
State of Missouri
Commissioned for Lincoln County
My Commission Expires: March 29, 2021
Commission Number: 13423262

Cindy L. Hohn

Date Commission Expires

March 29, 2021

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

February 15, 2019

Optime Care Inc,
4060 Wedgeway Ct
Earth City, MO 63045

Re: File Number 53-18-152029

Dear Licensee:

As set forth in the enclosed Order issued by the Disciplinary Subcommittee of the Michigan Board of Pharmacy, at least one administrative sanction has been imposed upon your license.

Section 16241(7) of the Michigan Public Health Code requires a licensee or registrant who is reprimanded, fined, placed on probation or ordered to pay restitution, or an individual whose application for licensure or registration is denied, to notify, in writing, the licensee or registrant's employer, if any, and each hospital the licensee/registrant is admitted to practice, if any, within *ten* days of the date of the order imposing the sanction(s)

The enclosed Notice of Licensure/Registration Sanction form has been developed to assist you in complying with these provisions of law.

By March 1, 2019, you are required to:

1) Complete the front of the form;
2) Transmit a copy of the form to the individuals and/or entities described above in section 16241(7);
3) Complete the affidavit on the back of the form;
4) Have the affidavit notarized; and
5) Submit the completed original form to the Department at the address below:

Michigan Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Attn: Compliance Section
P.O. Box 30670
Lansing, MI 48909

Failure to comply with these provisions of the Public Health Code may result in the imposition of further administrative sanctions.

If you have any questions regarding the enclosed form, please contact the Enforcement Division at (517) 335-3114.

Enclosures

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF PROFESSIONAL LICENSING
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

OPTIME CARE INC.
License Number: 53-06-004958,

Respondent.

File No. 53-18-152029

CONSENT ORDER

The Department of Licensing and Regulatory Affairs received evidence and information that Respondent Pharmacy violated the Public Health Code, MCL 333.1101 *et seq.* Specifically, Respondent Pharmacy distributed drugs in Michigan before obtaining a license to do so, in violation of MCL 333.17748(1).

MCL 333.17768(1) authorizes the Board's disciplinary subcommittee to take disciplinary action against a licensee who violates the Public Health Code. MCL 333.16231(5) authorizes the Department to submit a stipulation and final order to a disciplinary subcommittee for approval if an agreement is reached resolving alleged violations of the Public Health Code before the issuance of a complaint.

Respondent Pharmacy has admitted violating MCL 333.17748(1) and has agreed by the attached Stipulation that the Disciplinary Subcommittee may execute this Consent Order without detailing the facts and evidence substantiating the alleged violation(s) in a formal complaint.

The Disciplinary Subcommittee has reviewed this Order and agrees that the public interest is best served by resolution of this matter without further administrative process.

Therefore, IT IS FOUND that Respondent Pharmacy violated MCL 333.17748(1).

Accordingly, IT IS ORDERED that for the cited violation(s) of the Public Health Code, Respondent Pharmacy is FINED $5,000.00 payable to the state of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909. The fine shall be paid by check or money order, made payable to the state of Michigan, and the check or money order shall clearly display file number 53-18-152029.

IT IS FURTHER ORDERED that if Respondent Pharmacy fails to comply with the terms and conditions of this Order, Respondent Pharmacy's license shall be automatically SUSPENDED for a minimum of one day. If Respondent Pharmacy complies with this Order within six months of the suspension, the license shall be automatically reinstated. If Respondent Pharmacy's license remains suspended for more than six months, Respondent Pharmacy must apply for reinstatement of the license in accordance with MCL 333.16245 and 333.16247.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

Dated: 2/13/19

STIPULATION

1. Respondent Pharmacy admits violating MCL 333.17748(1) and acknowledges that the Department could prove the violation(s) with facts and evidence at an administrative hearing. Respondent agrees to resolve this matter by this Stipulation and Order without having the facts and evidence of the violation detailed in a formal complaint.

2. Respondent Pharmacy has had the opportunity to consult with an attorney and agrees to these terms voluntarily without duress of any kind.

3. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right provided by the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act, MCL 24.201 *et seq.*, to require the Department to prove the violation(s) of the Public Health Code by presentation of evidence and legal authority, and Respondent Pharmacy is

waiving the right to appear with an attorney and witnesses to present a defense to the allegations.

4. This Order resolves all pending issues in this matter and closes this case. No further action will be taken against Respondent Pharmacy based on the facts alleged herein, provided Respondent Pharmacy complies with all the terms of this Order.

5. This matter is a public record required to be published and made available to the public pursuant to the Michigan Freedom of Information Act, MCL 15.231 *et seq.*, and this action will be reported to the National Practitioner's Data Bank, and any other entity as required by state or federal law.

6. Factors taken into consideration in the formulation of this Order include the following:

> Respondent Pharmacy, based in Missouri, is a nationwide pharmacy licensed in all 50 states and is a wholesale distributor of a single drug, Korlym (mifepristone), used to treat patients with Cushing's syndrome. Due to an accidental oversight, Respondent Pharmacy inadvertently failed to obtain a Michigan license before distributing approximately 200 prescriptions of Korlym in Michigan from August 2017 to April 2018.
>
> Upon discovering the error during a quality assurance audit, Respondent Pharmacy immediately notified the Department and took steps to obtain the appropriate licenses. Respondent Pharmacy is now properly licensed to operate in Michigan. The Department has no evidence that Respondent Pharmacy acted intentionally to circumvent the law, that the drugs were defective in any way, or that, except for the lack of licensure, the drugs were improperly distributed.

7. This Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this matter.

8. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee. Respondent Pharmacy and the Department expressly reserve the right to further proceedings without prejudice should this Order be rejected.

AGREED TO BY:

Cheryl Wykoff Pezon, Director
Bureau of Professional Licensing
Department of Licensing and
Regulatory Affairs

Dated: 12-10-18

AGREED TO BY:

Donovan Quill, President and CEO,
Optime Care Inc.,
Respondent Pharmacy

Dated: 12/3/2018

IN THE MATTER OF:	)	
OPTIME CARE, INC.	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
Non-Resident Pharmacy Permit Number: 114730	)	**CASE NO: 22-L-0021**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **Optime Care, Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **Optime Care, Inc.** has violated the provisions of law based upon the conduct set out in the Statement.

2. **Optime Care, Inc.** shall pay an administrative fine in the amount of Five Thousand Dollars ($5000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **Optime Care, Inc.** attempt to discharge the same.

3. **Optime Care, Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-

20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **Optime Care, Inc.** further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **Optime Care, Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **Optime Care, Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **Optime Care, Inc.**'s permit, including, but not limited to revocation.

6. **Optime Care, Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. **Optime Care, Inc.** acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 14th of March, 2023.

Optime Care, Inc.

BY: [signature]

ITS: Financial Manager

DONE this the 15th of March, 2023.

ALABAMA STATE BOARD OF PHARMACY

By: [signature]
Robert M. Colburn, Jr., R.Ph., President

By: [signature]
Jennifer Muro Neumann,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

STACIA M. SILVA 6760
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: (808) 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

RECEIVED
BEFORE THE BOARD
2023 JAN -9 A 11:35
DEPT. OF COMMERCE
AND CONSUMER AFFAIRS
efiled 2023 Feb 14 a 08:35
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of OPTIME CARE INC., Respondent.	PHA 2022-41-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "2"

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s) and Respondent OPTIME CARE INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS.

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy (hereinafter the "Board") under miscellaneous permit number PMP 1209. The permit was issued on or about July 11, 2016. The permit is set to expire or forfeit on or about December 31, 2023.

2. Respondent's mailing address for purposes of this action is 4060 Wedgeway Court, Earth City, Missouri 63045.

3. On or about February 13, 2019, Respondent entered into a Consent Order in File No. 53-18-152029 (hereinafter the "Michigan Order") with the State of Michigan Board of

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

Pharmacy. A copy of the Michigan Order is attached hereto as Exhibit "1". The Michigan Order was based on Respondent distributing prescriptions in the state without a proper license. As a result, Respondent was fined $5,000.00.

4. On or about November 5, 2019, Respondent submitted a miscellaneous permit renewal application and responded "No" to the following question: "In the past 2 years has your license in this state or any other jurisdiction been formally disciplined by way of a fine, suspension, restriction, or revocation?"

5. On or about February 17, 2022, Respondent entered into a Consent Agreement in Case No. 22-0005 (hereinafter the "Louisiana Agreement") with the Louisiana Board of Pharmacy. A copy of the Louisiana Agreement is attached hereto as Exhibit "2". The Louisiana Agreement was based on Respondent's failure to properly report the Michigan Order. As a result, Respondent was issued a Letter of Reprimand and fined $5,000.00.

6. On or about March 15, 2022, Respondent reported the above-named disciplinary actions to the Board.

7. RICO alleges Respondent was disciplined by the States of Michigan and Louisiana and failed to timely report the Michigan Order to the Board.

8. RICO further alleges Respondent failed to report the Michigan Order on their 2019 renewal application.

9. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statutes: Hawaii Revised Statutes (hereinafter "HRS") §§ 436B-19(13) (disciplinary action by another state or federal agency), 436B-19(15) (failure to report disciplinary decision within thirty (30) days), and 461-21(a)(1) (procuring a license through fraud, misrepresentation, or deceit)

10. The Board has jurisdiction over the subject matter herein and over the parties hereto.

9 REPRESENTATIONS BY RESPONDENT.

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Earth City (City), MO (State), 12/29/2022 (Date).

OPTIME CARE INC.
Respondent

By: _____
(Signature)

Billy W. Oldham
(Print Name)

Its President, CFO, Treasurer, Secretary
(Print Title)

DATED: Honolulu, Hawaii, JAN 4 2023.

STACIA M. SILVA
Attorney for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF OPTIME CARE INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "2"; RICO CASE NO PHA 2022-41-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE
Chairperson

February 7, 2023
DATE

PATRICK ADAMS
Vice Chairperson

Mark Brown
MARK BROWN

CATALINA CROSS

KENT KIKUCHI

BRANDON RABANG

SHERI TOKUMARU

PVL.II.M22

Optime Care

July 3, 2023

VIA email
holly.handley@alaska.gov

VIA FedEx Express
Tracking No. 647145647887

State of Alaska Board of Pharmacy
ATTN: Holly Handley
550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567

RE: Optime Care Inc.
Case No.: 2023-000283 AMENDED

Dear Ms. Handley,

In response to the Amended Notice of Complaint against Optime Care Inc. ("Optime Care") that we received via email on June 20, 2023, a copy of which is attached, we provide the following information:

Item #1.
Submitting a Change of Pharmacist-in-Charge form on 02/22/2023 more than 10 days after the change of Pharmacist-in-Charge occurred.

This item was addressed in the letter emailed to you on May 15, 2023. See Attached.

Item #2.
Failure to notify the Board of a 2019 Michigan Disciplinary Action within 30 days and on the subsequent renewal application.

The Michigan Consent Order was executed by and between Optime Care and the Michigan Department of Licensing and Regulatory Affairs ("Michigan LARA") on February 13, 2019. At that time, Optime Care management had multiple conversations with Optime Care's outside counsel and the Michigan LARA. Through these conversations, it was the understanding of the Optime management personnel that the Consent Order was NOT a 'reportable' matter, and, therefore was not reported to the Alaska Board of Pharmacy.

At the time of the Alaska pharmacy license renewal in July of 2020, Optime Care's management team still believed that the Michigan matter did not need to be disclosed pursuant to communications with outside legal counsel and the Michigan LARA personnel.

In January of 2022, a Change of Ownership application was prepared and the interpretation of the Michigan matter under the NEW ownership was that the action should be disclosed to assure complete transparency and, as such, the Michigan action was disclosed on the Change of Ownership application in January of 2022.

Item #2 (continued)

At the time of the Alaska pharmacy license renewal in 2022, the person completing the renewal unfortunately misread/misinterpreted the question and thought that inasmuch as the Michigan matter had been disclosed on the change of ownership application, it did not need to be reported again. This omission was most certainly NOT intentional, but rather a misunderstanding as to what needed to be disclosed.

Item #3.
Failure to notify the Board of a 2022 Louisiana Disciplinary action within 30 days and on the subsequent renewal application.

Optime Care received the fully executed Consent Agreement from the Louisiana Board of Pharmacy on February 24, 2022. Written notification of the Consent Agreement was delivered to the Alaska Board of Pharmacy on March 16, 2022, which was within the 30 days notification requirement. See Attached.

Again, at the time of the Alaska pharmacy license renewal in 2022, the person completing the renewal application unfortunately misread/misinterpreted the question and thought that inasmuch as written notification of the Louisiana matter had been previously provided to the Alaska Board of Pharmacy, it did not need to be reported again. There was no intent to deceive or withhold information regarding the Louisiana action, but rather a misunderstanding as to what needed to be disclosed.

As the newly appointed General Manager of Optime Care, I can assure the Board that I am reviewing our regulatory compliance procedures with our Pharmacist-in-Charge and will make certain that all pharmacy personnel, including our licensure personnel, are properly trained on their respective duties. We apologize for our inadvertent misrepresentation on the pharmacy license renewal applications and, again, request that the Board exercise leniency and understanding on our behalf.

Should you have any questions, please contact me at 573-694-9962 or via email at brandon.salke@optimecare.com.

Thank you for your time and consideration.

Sincerely,

Brandon Salke
General Manager

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8162
Toll free fax: 907.269.8195

June 20, 2023

Email: brandon.salke@optimecare.com, julie.price@optimecare.com

Optime Care Inc.
Attn: Brandon Salke
4060 WEDGEWAY CT
EARTH CITY, MO 63045

Re: State of Alaska Board of Pharmacy- Case No.: 2023-000283

AMENDED NOTICE OF COMPLAINT

Dear Mr. Salke,

I am an Investigator with the State of Alaska, Division of Corporations, Business and Professional Licensing (Division) currently assigned to work with the Alaska Board of Pharmacy (Board).

The Division received a complaint against Optime Care Inc. which may be jurisdictional to the Board. This complaint alleges Optime Care Inc. may have violated the Alaska statutes and regulations governing the license by:

1. Submitting a Change of Pharmacist-in-Charge form on 02/22/2023 more than 10 days after the change of Pharmacist-in-Charge occurred,
2. Failure to notify the Board of a 2019 Michigan Disciplinary Action within 30 days and on the subsequent renewal application.
3. Failure to notify the Board of a 2022 Louisiana Disciplinary Action within 30 days and on the subsequent renewal application.

These allegations, which if substantiated, could result in disciplinary action against the license. As a regulatory agency, and on behalf of the Board, the Division is responsible for looking into such complaints.

This letter stands to inform you that Optime Care Inc. is the subject of a complaint and not the subject of an official investigation. At the conclusion of this inquiry, this complaint, along with all the materials and evidence gathered, will be presented to a licensed board member for review and disposition. If the reviewing board member finds Optime Care Inc.'s actions may constitute a violation of the statutes or regulations governing your license, this case will escalate to an official investigation, and that information may require disclosure on future applications and/or renewals. Should it progress to the point of an investigation, Optime Care Inc. will be formally notified.

You are instructed to contact the Division and provide the following documentation no later than **July 05, 2023:**

- A letter explaining the circumstances surrounding this complaint.
  - *This letter is your opportunity to provide additional information and respond to the allegations that you violated the statutes and/or regulations governing your license.*
- Any additional documentation you believe to be relevant to this complaint.

Your cooperation is requested to address this matter. Should you have any questions, you may contact me directly via email holly.handley@alaska.gov or telephone (907) 269-0356.

Respectfully,

Holly Handley, Investigator
State of Alaska, Board of Pharmacy

THE STATE of ALASKA

Department of Commerce, Community, and Economic Development

May 2, 2023

Email: julie.price@optimecare.com

AscellaHealth LLC dba Optime Care Inc
Attn: Julie Price
4060 WEDGEWAY CT
LAKE ST LOUIS, MO 63045

Re: State of Alaska Board of Pharmacy- Case No. 2023-001282

NOTICE OF COMPLAINT

Dear Ms. Price,

I am an Investigator with the State of Alaska, Division of Corporations, Business and Professional Licensing (Division) currently assigned to work with the Alaska Board of Pharmacy (Board).

The Division received a complaint against AscellaHealth LLC which may be jurisdictional to the Board. This complaint alleges AscellaHealth LLC may have violated the Alaska statutes and regulations governing the license by submitting a Change of Pharmacist-in-Charge form on 02.22.2023 more than 10 days after the change of Pharmacist-in-Charge occurred, which if substantiated, could result in disciplinary action against the license. As a regulatory agency, and on behalf of the Board, the Division is responsible for looking into such complaints.

This letter stands to inform you that AscellaHealth LLC is the subject of a complaint and not the subject of an official investigation. At the conclusion of this inquiry, this complaint, along with all the materials and evidence gathered, will be presented to a licensed board member for review and disposition. If the reviewing board member finds AscellaHealth LLC's actions may constitute a violation of the statutes or regulations governing your license, this case will escalate to an official investigation, and that information may require disclosure on future applications and or renewals. Should it progress to the point of an investigation, AscellaHealth LLC will be formally notified.

You are instructed to contact the Division and provide the following information no later than **May 22, 2023:**

- A letter explaining the circumstances surrounding this complaint
  - *This letter is your opportunity to provide additional information and respond to the allegations that you violated the statutes and or regulations governing your license.*
- Any additional documentation you believe to be relevant to this complaint

Your cooperation is requested to address this matter. Should you have any questions, you may contact me directly via email [redacted] or telephone (907) 269-0356.

Respectfully,

Holly Handley, Investigator
State of Alaska, Board of Pharmacy

Optime Care

May 11, 2023

VIA email
holly.handley@alaska.gov

VIA FedEx Express
Tracking No. 647145598120

State of Alaska Board of Pharmacy
ATTN: Holly Handley
550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567

RE: Optime Care Inc.
Case No.: 2023-000283

Dear Ms. Handley,

In response to the Notice of Complaint against Optime Care Inc. ("Optime Care") that we received via email on May 2, 2023, a copy of which is attached, we provide the following information:

At the time of the Pharmacist-in-Charge ("PIC") change from me, Brandon Salke, to Julie Price (effective 1/23/2023), we began the process of preparing and submitting the required notifications and forms to each Board of Pharmacy wherein Optime Care currently holds a pharmacy license (fifty states in total).

As you are most likely aware, each state Board of Pharmacy has its own timely filing requirements for a change in PIC, ranging from 7 days to 30 days. Inasmuch as there were fifty notifications/forms to prepare, our licensing department broke it down by separating the various state information and forms into working piles based on the regulatory time frame for submitting the appropriate notification and/or form, i.e., 7 days, 10 days, 15 days and 30 days. By doing so, we felt confident that the regulatory requirements for each state were being met.

Upon receiving your email informing us of the Notice of Complaint alleging that Optime Care may have violated the Alaska statues and regulation governing the license by submitting a Change of Pharmacist-in-Charge form more than 10 days after the change of PIC occurred, we began an investigation to determine the root cause for the delay in submitting the required form. Based upon our review and findings, we believe that after obtaining the required signatures on the Alaska form, it was inadvertently placed in the 30-day notification pile and sent out accordingly.

It was Optime Care's conscious and full intent to meet the timely filing requirements of each of the fifty states and we felt our method would accomplish this goal. Unfortunately, an inadvertent misplacement of the completed Alaska form, thwarted this effort.

Please note that we have developed an action plan to ensure that this does not happen again and have begun implementation of such. We are working with our Quality Assurance department to identify "tasks" for each state's PIC change requirements within our Electronic Quality Management System. This will allow us to assign specific tasks to individuals within the department and giving each the responsibility of ensuring that the assigned tasks are completed within the respective state's timeline. Additionally, this system will have each task reviewed and checked off by a second individual to confirm correct complete/submission of the notification and/or form.

We are truly sorry for our oversight in this matter and can only reiterate that we believed we made every effort to submit the required form in a timely manner. As such, we respectfully request that the Board exercise leniency and understanding in our behalf.

Should you have any questions, please contact me at 358-267-3917 extension 104 or via email at brandon.salke@optumcare.com.

Thank you for your time and consideration

Sincerely,

Brandon Salke
General Manager

Optime Care

March 10, 2022

VIA Federal Express
Tracking No. 7762 6616 9421

Alaska Board of Pharmacy
333 Willoughby Avenue, 9th Floor
Juneau, AK 99801

RE: Optime Care Inc.
Earth City, Missouri
Out-of-State Pharmacy License #190502

To Whom It May Concern,

This letter is sent as written notification of a Consent Agreement executed by and between Optime Care Inc. ("Optime") and the Louisiana Board of Pharmacy (the "LA Board"), received on February 24, 2022 with an effective date of February 17, 2022 (the "LA Agreement"). In settlement of Case No. 22-0005, a Letter of Reprimand was acknowledged in the Agreement and a fine in the amount of $5,000 was imposed. The fine was paid and the matter is closed.

The disciplinary action was taken against Optime by the LA Board due to Optime Care's failure to report a Consent Order executed by and between Optime and the Michigan Department of Licensing and Regulatory Affairs ("MI LARA") on its most recent Louisiana pharmacy license renewal application. The omission on the renewal application was not intentional on the part of Optime. Through conversations with the MI LARA and Optime's outside legal counsel at the time, it was the understanding of the Optime management personnel that the Consent Order was not a 'reportable' matter. The interpretation of the Michigan matter under Optime's new ownership was that the action should be disclosed to assure complete transparency and, as such, the Consent Order was reported on the recent change of ownership applications filed with various pharmacy boards, including the Louisiana and Alaska Boards.

A copy of the LA Agreement is enclosed for your reference.

Should you have any questions, please contact me at 801-942-2968 or via email at rhansen@rchconsult.com or Donovan Quill at 610-597-4221 or via email at donovan.quill@optimecare.com. Thank you,

Sincerely,

Robyn C Hansen
Regulatory Compliance

Enclosures

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

OPTIME CARE, INC.

LOUISIANA PHARMACY PERMIT NO. 7762 **Case No. 22-0005**

CONSENT AGREEMENT

WHEREAS, the Louisiana Board of Pharmacy received information confirming a Michigan Board of Pharmacy disciplinary action issued February 13, 2019 against OPTIME CARE, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7762, 4060 Wedgeway Ct., Earth City, MO 63045-1213.

WHEREAS, Respondent renewed its Louisiana pharmacy permit for Year 2020 without disclosing this disciplinary action as required.

WHEREAS, such action constitutes a violation of the following:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

LA. R.S. 37:1241(A)(6) Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another government agency, law enforcement agency, or court that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(22): Has failed to furnish to the board or representatives any information legally requested by the board.

To facilitate the submission of this Consent Agreement, Respondent agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **Louisiana Pharmacy Permit No. 7762 belonging to OPTIME CARE, INC.is issued a LETTER OF REPRIMAND.**

2. **OPTIME CARE, INC.is ordered to pay a fine of $5,000.00 and to reimburse the Board $250.00 for administrative costs, with total payment due the Board of $5,250.00, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Brenda Sellers, authorized to act on behalf of and acting on behalf of OPTIME CARE, INC., understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

SIGNED, AGREED TO AND ENTERED ON THIS 25th DAY OF January, 2022

OPTIME CARE, INC.
Louisiana Pharmacy Permit No. 7762

BY: Authorized Representative

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on February 17, 2022, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

Optime Care

Owner of Optime Care Inc. :
Innovative Specialty Solutions, LLC
1055 Westlakes Drive
Suite 200
Berwyn, PA 19312
FEIN: 93-3985400
100% Owner

Officers Optime Care Inc.:
Dea Belazi, Director

[redacted]

Bill Oldham, President

[redacted]

Optime Care Inc
4060 Wedgeway Ct. Earth City, MO 63045
Tel: 888-287-2017 Fax: 888-868-3147
www.OptimeCare.com

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OPTIME CARE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF JUNE, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "OPTIME CARE INC." WAS INCORPORATED ON THE SEVENTH DAY OF AUGUST, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5800132 8300

SR# 20252962925

Authentication: 203861250

Date: 06-04-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Optime Care Inc.

Pharmacy/Wholesaler License # (if applicable): WH02270 / PH03575

Physical Address: 4064 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Mailing Address (if different from physical address): 4060 Wedgeway Ct.

City: Earth City State: MO Zip: 63045

Telephone: 314-731-6900 Website: www.optimecare.com

Licensing Company Email: licensing@optimecare.com

Section 2: Personal Information

First: Amy Middle: Last: Kern

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St Charles Community College		08/2005 - 05/2026	
Address	**City**	**State**	**Zip**
4601 Mid Rivers Mall Dr	Cottleville	MO	63376
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Ft Zumwalt North High School		08/01 - 05/05	
Address	**City**	**State**	**Zip**
1230 Tom Ginnever Ave	O Fallon	MO	63366
Diploma/Degree obtained, if any			
diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16 - current	[redacted]			
10/10 - 11/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Optime Care Inc.		07/18 - current	
Business Address	**City**	**State**	**Zip**
4064 Wedgeway Ct.	Earth City	MO	63045
Phone	**Title**	**Number of Employed Hours**	
314-731-6900	Designated Rep / Pharmacy Fulfillment Mgr	~15,000 hours	

Description of Duties

Supervise, actively be involved with & aware of all distributor activities including receipt of product, drug shipments, inventory, returns, drug disposal/disposition, recordkeeping & training. Monitor state wholesale/distribution laws regularly.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Amy Kern, **certify that as the designated representative for**

Optime Care Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AEK I am at least 21 years of age;
3. AEK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AEK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AEK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AEK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AEK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Amy Kern

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Kern

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/19/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of St. Charles

I, Amy E. Kern, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/19/2025

Date

Subscribed and Sworn to before me this 19 day of November 2025

Rachel Christine Meyer

Notary Public Signature

RACHEL C MEYER
My Commission Expires
09-26-2026
NOTARY SEAL
St. Charles
County
Commission # 22877150
NOTARY PUBLIC - STATE OF MISSOURI
(Seal)

STATE OF MISSOURI
Division of Professional Registration

PHARMACY INSPECTION REPORT

BOARD OF PHARMACY
P.O. Box 625
JEFFERSON CITY, MO 65102
(573) 751-0091
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

Establishment License Number	2021049895
Establishment Name	Optime Care Inc
DBA Name	Optime Care Inc
Address	4060 Wedgeway Ct Earth City, Missouri 63045
Phone	(888) 287-2017
Email	legalrequests@ascellahealth.com
Person in Charge Name	Julie P Price
Person in Charge License Number	2012028246
Person In Charge Email Address	julie.price@OptimeCare.com
Current Inspection Date	05/02/2025
Inspector	Lisa Everett
Class	A,J,M
Profession	Pharmacy
Inspection Type	Routine
Inspection Reason	Routine
Inspection Result	No Violation

This report is based solely on the inspector's observations of a random sampling of the pharmacy's activities. Licensees should review Missouri and federal law to ensure compliance.

GENERAL INFORMATION

Question: Last controlled substance inventory
Answer: 1/1/25

Question: Administrations
Answer: No

Question: Sterile compounding
Answer: No

LICENSES AND REGISTRATION

Question: Pharmacy and individual licenses/registrations current, correct, and posted when required [20 CSR 2220-2.020(10); 2.020(5); 195.030.2; 21 CFR 1301.11]
Answer: Yes

Question: Notifications (offsite storage, remodels, disciplinary actions) submitted to the Board as required [20 CSR 2220-2.010(1)(I), (J); 2.020(4); 338.013.10, 383.133]
Answer: N/A

Question: Remote data entry site list maintained [20 CSR 2220-2.725(2)(A)]
Answer: Yes

Question: Other
Answer: N/A

PHARMACY OPERATIONS

Question: Sanitation maintained within the pharmacy and throughout the dispensing process [20 CSR 2220-2.010(1)(G)]
Answer: Yes

Question: Hot/cold water, sewage disposal available and functioning [20 CSR 2220-2.010(1)(G)]
Answer: Yes

Question: Adequate security maintained to deter drug theft and protect patient confidentiality [20 CSR 2220-2.010(1)(H), 20 CSR 2220-2.300(1)]
Answer: Yes

Question: Vacuum-tube delivery system working properly [20 CSR 2220-2.800]
Answer: N/A

Question: Automated dispensing/storage system meets requirements [20 CSR 2220-2.900]
Answer: N/A

Question: Automated filling system meets requirements [20 CSR 2220-2.950]
Answer: N/A

Question: Compliant with applicable policies and procedures requirements [various]
Answer: Yes

Question: Technicians and intern pharmacists properly supervised and work verified [20 CSR 2220-2.710; 2.010(1)(B)]
Answer: Yes

Question: Remote supervision meets requirements [20 CSR 2220-2.710, 2.725, 20 CSR 2220-6.055]
Answer: N/A

Question: Supervision of remote dispensing site meets requirements [20 CSR 2220-2.680]
Answer: N/A

Question: Medication take back activities comply with requirements [20 CSR 2220-2.095, 21 CFR 1317]
Answer: N/A

Question: Other
Answer: N/A

DRUG INVENTORY AND STORAGE

Question: Drug storage temperature in required range [20 CSR 2220-2.010(2)]
Answer: Yes

Question: Temperature measuring device present and functioning [20 CSR 2220-2.010(2)(A)]
Answer: Yes

Question: Drugs/devices properly separated from food/beverages [20 CSR 2220-2.010(2)(C)]
Answer: Yes

Question: Expired/misbranded/adulterated drugs separate from active inventory [20 CSR 2220-2.010(2)(B)]

Answer: Yes

Question: Return to stock prescriptions properly maintained and labeled [20 CSR 2220-3.040(3)]
Answer: N/A

Question: Repackaged drug container, labeling, and expiration dating meets requirements [20 CSR 2220-2.130(1)(B)(D)]
Answer: N/A

Question: Other
Answer: N/A

RECEIPT AND DISTRIBUTION OF DRUGS

Question: Receiving legend drugs from licensed entities [§ 338.315]
Answer: Yes

Question: Records maintained for receipt and distribution of legend drugs [20 CSR 2220-2.010(3)]
Answer: Yes

Question: Other
Answer: N/A

DISPENSING RECORDS

Question: Prescription hardcopy or images properly maintained [20 CSR 2220-2.010(3); 2.017; 2.018; 2.083]
Answer: Yes

Question: Dispensing records compliant with either manual or electronic recordkeeping requirements [20 CSR 2220-2.017; 2.080]
Answer: Yes

Question: Other
Answer: N/A

DISPENSING AND LABELING

Question: Sampled prescriptions dispensed as prescribed
Answer: Yes

Question: Sampled prescriptions comply with applicable dispensing laws [various]
Answer: Yes

Question: Generic substitutions meet requirements [338.056]
Answer: Yes

Question: Prescription labels contain required information [338.059]
Answer: Yes

Question: Child resistant packaging present [16 CFR 1700.14]
Answer: Yes

Question: Return to stock items properly reversed in computer system [20 CSR 2220-3.040(3)]
Answer: N/A

Question: Prescription transfers properly executed and documented [20 CSR 2220-2.120]
Answer: N/A

Question: Required counseling offer made to each patient [20 CSR 2220-2.190(1)]
Answer: Yes

Question: Automated Filling System properly checked by pharmacist [20 CSR 2220-2.950(4)]
Answer: N/A

Question: Other
Answer: N/A

LONG-TERM CARE DISPENSING

Question: Packaging meets requirements [20 CSR 2220-2.140(2)(C)]
Answer: N/A

Question: Sampled labels meet requirements [20 CSR 2220-2.140(2)(B)]

Answer: N/A

Question: Proper return and reuse of medication [20 CSR 2220-3.040]
Answer: N/A

Question: Proper label changes for previously dispensed prescriptions [20 CSR 2220-2.140(2)(B)]
Answer: N/A

Question: Proper dispensing records maintained [20 CSR 2220-2.010(3); 2.080; ; 2.140]
Answer: N/A

Question: Other
Answer: N/A

MULTI-MED DISPENSING

Question: Packaging and containers meet requirements [20 CSR 2220-2.145(2)(C)(D)]
Answer: N/A

Question: Labeling meets requirements [20 CSR 2220-2.145(2)]
Answer: N/A

Question: Return and reuse meets requirements [20 CSR 2220-2.145(2)(H)]
Answer: N/A

Question: Proper dispensing records maintained [20 CSR 2220-2.145(2)(F); 20 CSR 2220-2.080; 20 CSR 2220-2.010(3)]
Answer: N/A

Question: Other
Answer: N/A

CONTROLLED SUBSTANCES

Question: Sampled prescriptions comply with controlled substance laws/rules [various]
Answer: N/A

Question: Controlled substance records maintained as required [various]
Answer: N/A

Question: Loss reports properly filed [19 CSR 30-1.034(2)(B); 21 CFR 1301.76(b)]
Answer: N/A

Question: Annual controlled substance inventory complete and taken when required [19 CSR 30-1.042]
Answer: Yes

Question: Pharmacist-in-charge change inventory taken [20 CSR 2220-2.090(2)(T)]
Answer: N/A

Question: 222 forms and CSOS properly executed and maintained [21 CFR 1305]
Answer: N/A

Question: C-II drugs under lock/secure cabinet [19 CSR 30-1.034]
Answer: N/A

Question: C-III to IV drugs dispersed in inventory or under lock/secure cabinet [19 CSR 30-1.034(1)]
Answer: N/A

Question: Other
Answer: N/A

PSEUDOEPHEDRINE SALES

Question: Schedule V OTC pseudoephedrine products behind counter or under lock [19 CSR 30-1.034]
Answer: N/A

Question: Combat Meth Act self-certification current [21 CFR 1306.8]
Answer: N/A

Question: OTC pseudoephedrine sales properly entered into database and accessible [19 CSR 30-1.074]
Answer: N/A

Question: Other
Answer: N/A

PHARMACIST ADMINISTRATION

Question: Immunization protocol compliant, complete, current, signed/dated, and followed [20 CSR 2220-6.050(4)]
Answer: N/A

Question: Administration records properly maintained [20 CSR 2220-6.050(6)]
Answer: N/A

Question: Other
Answer: N/A

PHARMACY CLINICAL SERVICES

Question: Pharmacist prescribing meets requirements [338.665; 20 CSR 2220-6.200]
Answer: N/A

Question: Medication Therapy Services meet requirements [20 CSR 2220-6.070; 6.080]
Answer: N/A

Question: Other
Answer: N/A

NON-STERILE COMPOUNDING

Question: Compounding equipment functioning/maintained [20 CSR 2220-2.400(5)(C)]
Answer: N/A

Question: Full active/therapeutic ingredients names on prescription container [20 CSR 2220-2.400(7)(F)]
Answer: N/A

Question: Compounding log and records maintained as required [20 CSR 2220-2.400(7)]
Answer: N/A

Question: Batch/bulk compounds, including return to stock prescriptions, labeled with lot number and beyond-use date [20 CSR 2220-2.400(7)(A)(D)]
Answer: N/A

Question: Adverse effects/complaints documented and investigated [20 CSR 2220-2.400(8)(B)]
Answer: N/A

Question: Recalls and prescriber/patient notifications conducted when required [20 CSR 2220-2.400(8)(C)]
Answer: N/A

Question: Other
Answer: N/A

OTHER PHARMACY VIOLATIONS
Question: Are there any other violations?
Answer: N/A

OTHER COMMENTS

ACKNOWLEDGED BY	**DATE**
Bill Bertetto	05/02/2025
INSPECTOR'S SIGNATURE	**DATE**
Lisa Everett	05/02/2025

State of Missouri

Division of Professional Registration

Pharmacy

Class A, J, M

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2025017801
OPTIME CARE INC.
OPTIME CARE INC.
4060 WEDGEWAY COURT
EARTH CITY MO 63045
UNITED STATES

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Pharmacy

Class A, J, M

VALID THROUGH OCTOBER 31, 2027
ORIGINAL CERTIFICATE/LICENSE NO. 2025017801
Sergio Barranco Medina - 2016019830

OPTIME CARE INC.
OPTIME CARE INC.
4060 WEDGEWAY COURT
EARTH CITY MO 63045
UNITED STATES

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

Back to Licensee Search Page

Licensee Details

License

LICENSEE NAME
Optime Care Inc.

PROFESSION NAME
Pharmacy

LICENSE NUMBER
2025017801

EXPIRATION DATE
10/31/2027

ORIGINAL ISSUE DATE
5/21/2025

CURRENT DISCIPLINE STATUS
None

CLASSIFICATION
Class A (Community/Ambulatory) ;Class J (Shared Services);Class M (Specialty Bleeding Disorder)

PRACTITIONER DBA NAME
Optime Care Inc.

PERSON IN CHARGE NAME
Sergio Barranco Medina

PREVIOUS DISCIPLINARY ACTIONS
No

Address

STREET	CITY	STATE	POSTALCODE
4060 Wedgeway Court	Earth City	Missouri	63045

COUNTY
St. Louis County

Board Details

BOARD NAME	ADDRESS	CITY	STATE
Missouri Board of Pharmacy	3605 Missouri Boulevard P.O. Box 625	Jefferson City	MO

ZIP CODE	PHONE	TTY	VOICE RELAY
65102-0625	(573) 751-0091	(800) 735-2966	(800) 735-2466

WEBSITE	EMAIL
pr.mo.gov/pharmacists	missouribop@pr.mo.gov

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FO1061477	12-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-04-2024

OPTIME CARE INC
4060 WEDGEWAY CT
EARTH CITY, MO 63045

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FO1061477	12-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-04-2024

OPTIME CARE INC
4060 WEDGEWAY CT
EARTH CITY, MO 63045

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4JJJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FP5422441
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	■ Other: SPECIALTY PHARMACY	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH PH04722		☐ Hospital
			■ Other: SPECIALTY PHARM

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: PHARMA FUSION LLC

Physical Address: 2580 HWY 95 STE 218

City: BULLHEAD CITY State: AZ Zip: 86442

Mailing Address (if different from physical address): SAME AS PHYSICAL

City: _____ State: _____ Zip: _____

Telephone: (928) 876-0158 Toll Free # (NAC 639.708, NRS 639.23286): (888) 341-6119

Fax: (928) 543-2082 Contact Email: SROY@PHARMAFUSIONRX.COM

Website: WWW.PHARMAFUSIONRX.COM

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): ERIC L O'NEAL

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: SAJAL K. ROY, PHARM.D	NV Pharmacist Registration #: 19175
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: LOUISIANA

Parent Company (if any): PHARMA FUSION HOLDINGS, INC.

Corporation/Organization Name: PHARMA FUSION LLC

Mailing Address: 518 PUJO STREET

City: LAKE CHARLES State: LA Zip: 70601

Telephone: (337) 761-5397 Email: SROY@PHARMAFUSIONRX.COM

Contact Person Name: SAJAL K. ROY, PHARM.D.

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☑ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PHARMACIST-IN-CHARGE (title) for PHARMA FUSION LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

ERIC L. O'NEAL, PHARM.D.

Print Name of Authorized Person

Eric L O'Neal

Original signature of Authorized Person (copies or stamps not accepted)

1/13/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, ERIC L. O'NEAL hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST-IN-CHARGE (title) for PHARMA FUSION LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

ERIC L. O'NEAL, PHARM.D.
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of January, 2026

Tanya Lynn Milby
Notary Public

TANYA LYNN MILBY
Notary Public - State of Florida
Commission # HH 510767
My Comm. Expires Apr 1, 2028
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SAJAL K. ROY, PHARM.D.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Sajal Roy

Original signature of Authorized Person (copies or stamps not accepted)

1/13/26

Date

Board Use Only	Date Received: 1115126	Amount: $500 CK 3243

UNITED STATES OF AMERICA

State of Louisiana

Nancy Landry

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

PHARMA FUSION LLC

A limited liability company domiciled in LAKE CHARLES, LOUISIANA,

Filed charter and qualified to do business in this State on June 12, 2024,

I further certify that the records of this Office indicate the company has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned, is in good standing and is authorized to do business in this State.

I further certify that this certificate is not intended to reflect the financial condition of this company since this information is not available from the records of this Office.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

January 8, 2026

Nancy Landry

Secretary of State

Web 45975900K

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Certificate ID: 12134985#XYN83

To validate this certificate, visit the following web site, go to **Business Services**, **Search for Louisiana Business Filings**, **Validate a Certificate**, then follow the instructions displayed.
www.sos.la.gov

PHARMA FUSION HOLDINGS, INC.
518 Pujo Street
Lake Charles, LA 70601

OWNERSHIP

Sajal K. Roy, Pharm.D.
56.68%

[redacted]

Harold E. Cannon
40.41%

John DeWolf
1.24%

[redacted]

Harpreet Mann
1.04%

Armando Serrano
0.62%

[redacted]

OFFICERS

Sajal K. Roy, Pharm.D.,
President/Director

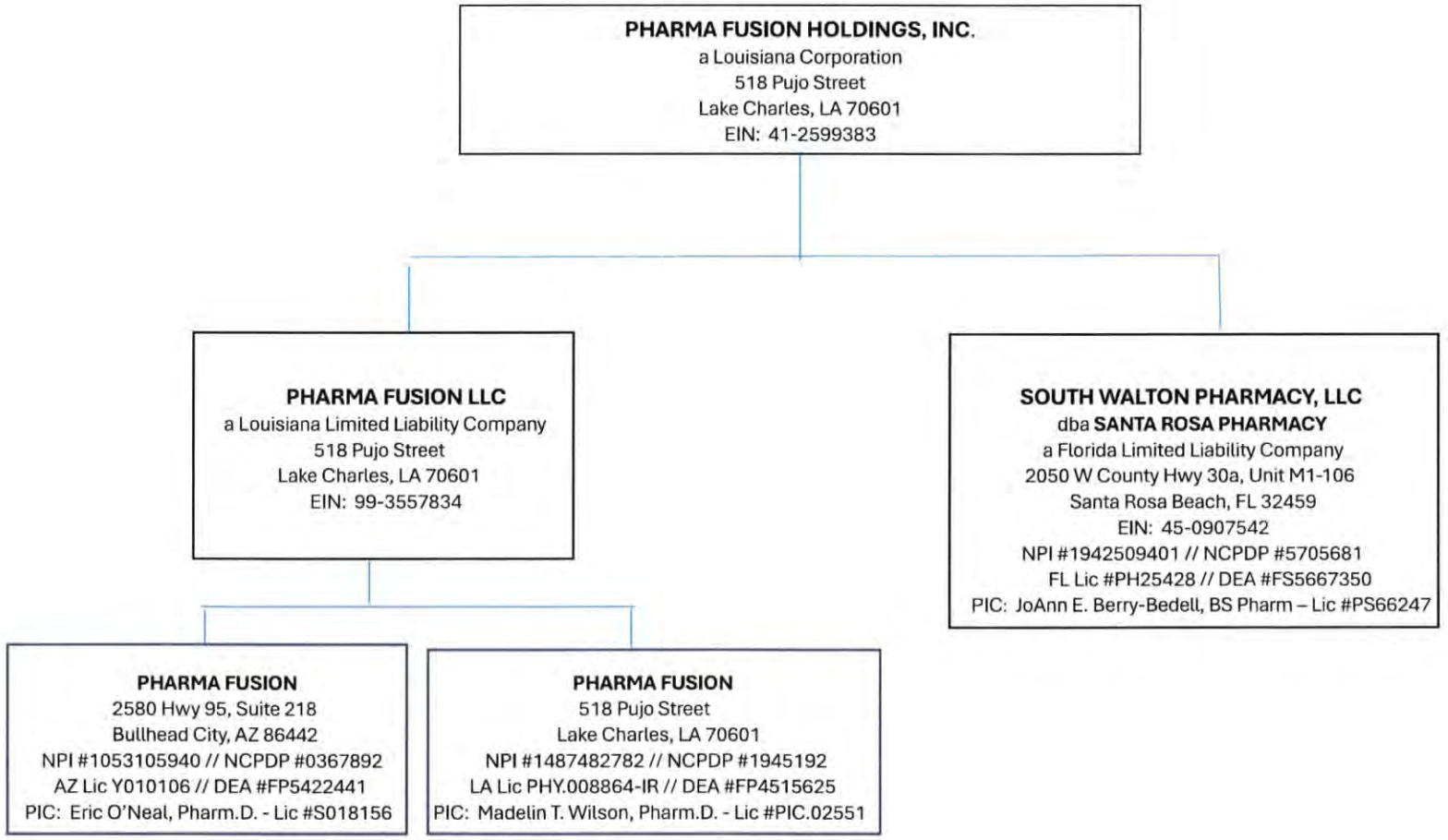
Richard A. Rodrigue, Pharm.D.,
Chief Executive Officer

Nicholas Self,
Chief Operations Officer

Caitlin Henderson,
Chief Administrative Officer

pharma fusion

ORGANIZATIONAL STRUCTURE



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PHARMA FUSION LLC

Pharmacy/Wholesaler License # (if applicable) PH04722

Physical Address 2580 HWY 95, SUITE 218

City BULLHEAD CITY State AZ Zip 86442

Mailing Address (if different from physical address) SAME AS PHYSICAL

City _____ State _____ Zip _____

Telephone (928) 876-0158 Website WWW.PHARMAFUSIONRX.COM

Licensing Company Email LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First ERIC Middle L Last O'NEAL

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY OF HEALTH SCIENCES			08/07 TO 06/10	
Address		City	State	Zip
11 SUNSET WAY		HENDERSON	NV	89014
Diploma/Degree obtained, if any				
DOCTOR OF PHARMACY				
School Name			From - To (MM/YY – MM/YY)	
OAKTON COMMUNITY COLLEGE			08/03 TO 06/07	
Address		City	State	Zip
1600 E GOLF ROAD		DES PLAINES	IL	60016
Diploma/Degree obtained, if any				
PRE-PHARMACY COURSEWORK				
School Name			From - To (MM/YY – MM/YY)	
MAINE SOUTH HIGH SCHOOL			08/96 TO 06/98	
Address		City	State	Zip
1111 S DEE ROAD		PARK RIDGE	IL	60068
Diploma/Degree obtained, if any				
HIGH SCHOOL				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PHARMA FUSION LLC			08/25 TO CURRENT	
Business Address		City	State	Zip
2580 HWY 95 STE 218		BULLHEAD CITY	AZ	86442
Phone	Title		Number of Employed Hours	
928-876-0158	PHARMACY MANAGER		840	
Description of Duties				
RECEIVE PRESCRIPTIONS, MAINTAIN INVENTORY, DISPENSE MEDICATION, ADHERE TO BOARD OF PHARMACY RULES AND REGULATIONS, VERIFY CORRECT DRUG UTILIZATION, BILL INSURANCES FOR SERVICES				

Business Name			From - To (MM/YY – MM/YY)	
WALMART PHARMACY			06/12 TO CURRENT	
Business Address		City	State	Zip
2840 HWY 95		BULLHEAD CITY	AZ	86442
Phone	Title		Number of Employed Hours	
928-758-3447	STAFF PHARMACIST-PRN		22,880 PLUS	
Description of Duties				
PHARMACY MANAGER FOR 11 YEARS, HIRE AND TRAIN STAFF, INVENTORY MANAGAMENT, EDUCATE PATIENT ON SAFE USE OF MEDICATION, ADHERE TO AND IMPLEMENT POLICIES AND PROCEDURES, ANNUAL INVENT.				

Business Name			From - To (MM/YY – MM/YY)	
WALGREENS PHARMACY			06/10 TO 06/12	
Business Address		City	State	Zip
1305 S GREENFIELD ROAD		MESA	AZ	85206
Phone	Title		Number of Employed Hours	
480-830-9266	STAFF PHARMACIST		4,160	
Description of Duties				
COMPOUND MEDICATION (SUSPENSIONS, CAPSULES, CREAMS), RECEIVE AND DISPENSE MEDICATION, DUR REVIEWS, INVENTORY MANAGEMENT, COUNSEL PATIENTS ON SAFE USE OF MEDICATION.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, ERIC L ONEAL, **certify that as the designated representative for**

PHARMA FUSION LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ELO I am at least 21 years of age;
3. ELO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ELO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ELO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ELO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ELO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

ERIC L ONEAL

Print Name (First, Last)

Eric L ONeal

Original Signature (electronic, copies or stamps not accepted)

~~01/02/2026~~ 11/6/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ERIC L ONEAL

Print Name (First, Last)

Eric L ONeal — 1/6/2026

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Mohave

I, Eric L ONeal, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Eric L ONeal — 1/6/2026

Original Signature — **Date**

Subscribed and sworn to before me this 6th day of January 2026

Notary Public Signature

CHADRICK CASTEEL
Notary Public - Arizona
Mohave County
My Commission Expires
10/17/2028
Commission # 676190

(Seal)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y010106	10/31/2026	Pharma Fusion, LLC
Address :		
2580 Hwy 95		
Zip :	City :	State :
86442	Bullhead City	AZ
Phone :	Fax :	Email :
(928) 876-0185	(928) 543-2082	sroy@pharmafusionrx.com
Inspection Date :	PIC :	Pic License Exp Date :
05/22/2025	Sajal Roy	10/31/2025
DEA # :	DEA # Exp. date :	Inspection Reviewed With :
[redacted]	03/31/2028	Sajal Roy
Reviewers License# :	Inspection type :	
S021767	Opening	

Inspection Conducted By :

Chirag Patel

ACTIVITIES

1	Nonsterile Compounding	☐ YES	☑ NO
2	Nonsterile Hazardous Compounding	☐ YES	☑ NO
3	Sterile Compounding	☐ YES	☑ NO
4	Sterile Hazardous Compounding	☐ YES	☑ NO

Hospital Facility Data

# Licensed Beds	DHS License #
N/A	N/A

PHARMACY DEPARTMENT

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Size/Personnel 313 sq ft. Has more room to expand (within the same facility) in the future if needed.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
2	Shelves	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Design-efficient, safe pharmacy practice	☑ S ☐ C/P ☐ U ☐ N/A	R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
4	Counter	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Aisles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(D)
7	Enclosed (barrier)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
9	Lighting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
10	Temperature controlled/Ventilation	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Working counter barrier	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(H)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

12	Receiving/checking area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(F)
14	Walls	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area No plans for compounding.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410(E)

SECURITY

1	Controlled substances No plans to stock any controlled substances in the near future.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

2	Pharmacist access	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Additional pharmacy drug storage areas	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Therapeutics reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Drug compatibility reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Drug product equivalency reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Sterile products reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)
6	Policy and procedure manual-pharmacy operations	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)
7	Policy and procedure manual-technicians	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)

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8	Policy and procedure manual-automation	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04
9	Policy and procedure manual-compounding	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410; R4-23-670
10	Arizona statutes/rules	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Current antidote/drug interaction information	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
12	Poison Control # displayed	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

PHARMACY EQUIPMENT/FORMS

1	Refrigerator	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Freezer	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Computer-security/data storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408
4	Computer-patient profiles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(3)
5	Computer-single drug usage report	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(4)
6	Computer-pharmacist log book/hard copy print out	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(C)(4)

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7	Prescription label ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)	☑ S ☐ C/P ☐ U ☐ N/A	
8	Federal transfer labels R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)	☐ S ☐ C/P ☐ U ☑ N/A	
9	Warning labels R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)	☑ S ☐ C/P ☐ U ☐ N/A	
10	Written patient information R4-23-402(C)(4); R4-23-402(I)	☑ S ☐ C/P ☐ U ☐ N/A	
11	Consultation log R4-23-402(G)	☑ S ☐ C/P ☐ U ☐ N/A	
12	Federal medication guides 21 CFR part 208	☑ S ☐ C/P ☐ U ☐ N/A	
13	Hospital IV label R4-23-658	☐ S ☐ C/P ☐ U ☑ N/A	
14	Generic Rx blanks R4-23-402(A); R4-23-407(D)	☑ S ☐ C/P ☐ U ☐ N/A	
15	Immunization administration recordkeeping R4-23-411(F) No plans for immunizations in the near future.	☐ S ☐ C/P ☐ U ☑ N/A	
16	Schedule V register R4-23-612(A)(2)	☐ S ☐ C/P ☐ U ☑ N/A	
17	Methamphetamine precursor sales log ARS 32-1977	☐ S ☐ C/P ☐ U ☑ N/A	

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18	Red C stamp	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting PIC will be setting up account with PMP department.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-502
20	Graduates	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
25	Weights for Rx balance	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)

29	Mechanical storage and counting device	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-615
30	Mechanical counting device	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-616
31	Emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size No plans for sterile compounding.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(2)
4	Restricts entry/access	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(4)

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6	Nonporous and cleanable floor	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
9	Environment ISO 7	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(6)
10	Hood ISO 5	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

-Open door pharmacy mainly mailing out patient specific injectable drugs used for infusions, to practitioner's office and patient's home for infusion servic
es
administered by trained medical personnel.
-No sterile or non-sterile compounding is anticipated at this location.
-No controlled substances are anticipated to be dispensed from this location.
-Pharmacy has a current DEA registration and will perform ACSI every year on May 1st as required.

-Pharmacy hours will be M-F 9a-5:30pm. Closed on weekends.

-Opening Inspection Rating: Satisfactory.

Handouts Provided:
- All licensees must update contact Information (ARS 32-1926).
- Continuing Education AUDIT Information.
- Continuing Education Requirements.
- Prescriptive Authority Chart.
- Prescription Requirements for Immunizations.
- Controlled substance loss/DEA 106 reporting reminder.
- Arizona Standing Order for Naloxone. (2024-2025).
- Ephedrine Letter.
- Practice of Flavoring.
- 2020-2024 Statute/Rule Changes Summary.
- Pharmacy reporting for two or more anti-tuberculosis medications.
- Prescription Monitoring Program.
- Protecting yourself from SCAMS.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 03/15/2025
Receipt Number: 2025196106
Receipt Amount $: 480.00

Pharmacy - Independent

PERMIT NO
Y010106

EXPIRES
10/31/2026

Issued to : Pharma Fusion, LLC
Sajal Roy
2580 HWY 95 SUITE 218 BULLHEAD CITY, AZ 86442

Pharma Fusion, LLC
2580 HWY 95 SUITE 218
BULLHEAD CITY, AZ 86442

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Pharma Fusion, LLC
LICENSE NUMBER : Y010106
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

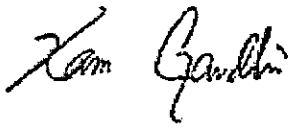
Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	PHARMA FUSION LLC
Address :	2580 HIGHWAY 95 SUITE 218 BULLHEAD CITY AZ 86442
Registration No :	Y010322
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	12/16/2025
Expiration Date :	10/31/2027
Status :	FINAL PROCESSING
Discipline :	No



Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 01/08/2026

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Pharma Fusion, LLC
Address :	2580 Hwy 95 Suite 218 Bullhead City AZ 86442
Registration No :	Y010106
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	05/22/2025
Expiration Date :	10/31/2026
Status :	OPEN
Discipline :	No

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PHARMA FUSION LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04722

Physical Address 2580 HWY 95, SUITE 218

City BULLHEAD CITY State AZ Zip 86442

Mailing Address (if different from physical address) 518 PUJO STREET

City LAKE CHARLES State LA Zip 70601

Telephone (337) 761-5397 Website WWW.PHARMAFUSIONRX.COM

Licensing Company Email LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First John Middle Thomas Martin Last DeWolf

Alias(es, nicknames, aliases, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
St. Charles East HS.			1996 - 2000	
Address		**City**	**State**	**Zip**
1020 Dunham Rd		St. Charles	IL	60174
Diploma/Degree obtained, If any				
Diploma				

School Name			From - To (MM/YY – MM/YY)	
Triton College			2007 - 2009	
Address		**City**	**State**	**Zip**
2000 5th Ave		River Grove	IL	60171
Diploma/Degree obtained, If any				

School Name			From - To (MM/YY – MM/YY)	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, If any				

School Name			From - To (MM/YY – MM/YY)	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, If any				

School Name			From - To (MM/YY – MM/YY	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, If any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
07/11 – Current	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Pharma Fusion				From - To (MM/YY – MM/YY): 06/25 - Current
Business Address: 518 Fuji ST	City: Lake Charles	State: LA	Zip: 70601	
Phone: 337-761-5397	Title: VP of Bleeding Disorders			
Description of Duties: Manage Sales Team for Entire Country, Work w/ Chapters + National org.				

Business Name: Care Partners				From - To (MM/YY – MM/YY): 06/23 – 06/25
Business Address: 326 Peterson Rd	City: Liberty ville	State: IL	Zip: 60048	
Phone: 866-852-0202	Title: Sales Rep			
Description of Duties: Manage patients on service, sell pharmacy services				

Business Name: Inducare				From - To (MM/YY – MM/YY): 10/18 - 06/23
Business Address: 2400 Veterans Memorial Blvd	City: Kenner	State: LA	Zip: 70062	
Phone: 877-327-8881	Title: Director			
Description of Duties: Manage Sales Team, Sell Pharmacy Services				

Business Name: Affinity Biotech (dba Diplomat)				From - To (MM/YY – MM/YY): 05/09 - 09/18
Business Address: 4100 Saginaw St.	City: Flint	State: MI	Zip: 48507	
Phone:	Title:			
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:	
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John DeWolf

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/5/26

Date

Please have this section completed in the presence of a Notary Public.

State of LOUISIANA, ss. County of PARISH ST. TAMMANY

I, John DeWolf, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/26

Date

Subscribed and Sworn to before me this 6 day of January.

Notary Public Signature SCOTT RUEC

#27078

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PHARMA FUSION LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04722

Physical Address 2580 HWY 95, SUITE 218

City BULLHEAD CITY State AZ Zip 86442

Mailing Address (if different from physical address) 518 PUJO STREET

City LAKE CHARLES State LA Zip 70601

Telephone (337) 761-5397 Website WWW.PHARMAFUSIONRX.COM

Licensing Company Email LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First Harpreet Middle Singh Last Maan

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
California State University, Chico			01/02 - 12/06	
Address	City		State	Zip
400 W. 1st	Chico		CA	95929
Diploma/Degree obtained, if any				
Business Administration Degree				
School Name			From - To (MM/YY – MM/YY)	
Yuba City High School			01/98 - 01/02	
Address	City		State	Zip
850 B st.	Yuba City		CA	95991
Diploma/Degree obtained, if any				
High School diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
04/25 - 01/26	[redacted]			
01/24 - 03/25				
05/21 - 01/24				
01/19 - 05/21				
08/17 - 01/19				
09/09 - 08/17				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Pharma Fusion, LLC			From - To (MM/YY – MM/YY): 01/26-01/26	
Business Address: 518 Pujo St.	City: Lake Charles		State: LA	Zip: 70601
Phone: 337-764-5597	Title: Vice President of Strategy			
Description of Duties: Develope annual and all Strategy to foster future growth				
Business Name: Santa Rosa Pharmacy			From - To (MM/YY – MM/YY): 02/24-12/25	
Business Address: 2950 W. County Hwy 30A MJ-106	City: Santa Rosa Beach		State: FL	Zip: 32459
Phone: 850-622-3313	Title: Vice President of Strategy			
Description of Duties: Develop annual and all Strategy to foster future growth.				
Business Name: Octapharma			From - To (MM/YY – MM/YY): 01/19-01/24	
Business Address: 117 W. Century Rd.	City: Paramus		State: NJ	Zip: 07652
Phone: 201-604-1130	Title: Coagulation Sales Specialist			
Description of Duties: Mgmt of Sales in AL, WA, OR, N-CA, LFD				
Business Name: Drug Co Pharmacy			From - To (MM/YY – MM/YY): 01/17-01/19	
Business Address: 107 Smith Church Rd	City: Roanoke Rapids		State: NC	Zip: 27870
Phone:	Title: Western Sales Manager			
Description of Duties: Responsable for whole western 1/2 of USA Sales				
Business Name: Hemophilia Support Systems			From - To (MM/YY – MM/YY): 01/16-01/17	
Business Address: 5727 Lincoln Ave.	City: Cypress		State: CA	Zip: 90630
Phone: 888-439-4366	Title: Sales Manager			
Description of Duties: Mgmt of all Sales for Company				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Guided Alliance Healthcare Services			01/07 - 01/16
Business Address	**City**	**State**	**Zip**
2711 Aliso Creek Rd. Ste 185a	Aliso Viejo	CA	92656
Phone	**Title**		
949-496-4106	District Manager		
Description of Duties			
Mgmt of Call Sales			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Harpreet, Maan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Walton.

I, Harpreet, Maan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Harpreet Maan

Original Signature

1-5-2026

Date

Subscribed and Sworn to before me this 5th day of January.

Tanya Lynn Milby

Notary Public Signature

TANYA LYNN MILBY
Notary Public - State of Florida
Commission # HH 510767
My Comm. Expires Apr 1, 2028
Bonded through National Notary Assn.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PHARMA FUSION LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04722

Physical Address 2580 HWY 95, STE 218

City BULLHEAD CITY State AZ Zip 86442

Mailing Address (if different from physical address) 518 PUJO STREET

City LAKE CHARLES State LA Zip 70601

Telephone (337) 761-5397 Website WWW.PHARMAFUSIONRX.COM

Licensing Company Email LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First SAJAL Middle K Last ROY

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Ema[redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
WISSIHICKON HIGH SCHOOL		1994-1998	
Address	**City**	**State**	**Zip**
531 HOUSTONN ROAD	AMBLER	PA	19002
Diploma/Degree obtained, if any			
H.S. DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE SCIENCES		1998-2004	
Address	**City**	**State**	**Zip**
600 S 43 STREET	PHILADELPHIA	PA	19104
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
08/2018-PRESENT				
From - To (MM/YY – MM/YY)				
03/2016-07/2018				
From - To (MM/YY – MM/YY)				
02/2012-02/2016				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
PHARMA FUSION HOLDINGS, INC.			12/31/2025-PRESENT	
Business Address	**City**		**State**	**Zip**
518 PUJO STREET	LAKE CHARLES		LA	70601
Phone	**Title**			
(337) 761-5397	PRESIDENT/DIRECTOR			
Description of Duties				
RESPONSIBLE FOR OVERSIGHT OF ALL COMPANY/PHARMACY OPERATIONS				

Business Name			From - To (MM/YY – MM/YY)	
PHARMA FUSION LLC			06/2024-PRESENT	
Business Address	**City**		**State**	**Zip**
518 PUJO STREET	LAKE CHARLES		LA	70601
Phone	**Title**			
(337) 761-5397	CEO/PIC			
Description of Duties				
OVERSIGHT OF ALL COMPANY OPERATIONS & DISPENSING ACTIVITIES				

Business Name			From - To (MM/YY – MM/YY)	
INFUCARE RX INC/FACTOR ONE SOURCE/FAST PHARMACY			01/2019-01/2021	
Business Address	**City**		**State**	**Zip**
2400 VETERANS MEMORIAL BLVD, STE 480	KENNER		LA	70062
Phone	**Title**			
(877) 327-8881	OWNER/VP OF OPERATIONS			
Description of Duties				
RESP FOR OVERSIGHT OF ALL OPERATIONS/DISPENSING ACTIVITIES				

Business Name			From - To (MM/YY – MM/YY)	
FACTOR ONE SOURCE/FAST PHARMACY			03/2014-12/2018	
Business Address	**City**		**State**	**Zip**
300 GLEN STREET	CUMBERLAND		MD	21502
Phone	**Title**			
(844) 733-6779	CEO/OWNER			
Description of Duties				
OVERSIGHT OF ALL COMPANY OPERATIONS/ DISPENSING ACTIVITIES				

Business Name			From - To (MM/YY – MM/YY)	
WESTERN MARYLAND HEALTH SYSTEM (WMHS)			2014-2015	
Business Address	**City**		**State**	**Zip**
12500 WILLOWBROOK ROAD	CUMBERLAND		MD	21502
Phone	**Title**			
(240) 964-1399	EXEC DIR OF CLINICS & PRACTICES/PHARMACY SERVICES			
Description of Duties				
OVERSIGHT & DEVELOPMENT OF 20 PRIMARY, URGENT & SPECIALTY CARE OFFICES FORMATION OF ACO WITH 10,000 LIVES				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
WESTERN MARYLAND HEALTH SYSTEMS (WMHS)			2012-2014	
Business Address		City	State	Zip
12500 WILLOWBROOK ROAD		CUMBERLAND	MD	21502
Phone	Title			
(240) 964-1399	DIR OF PHARMACY SERVICES/DIRECTOR OF QUALITY/COMPLIANCE			
Description of Duties				
OVERSIGHT INPATIENT & CLINICAL PHARM. PROGRAMS/OUTPATIENT PHARMACY SVCS. DEVEL/MONITOR QUALITY INITIATIVES; COMPLIANCE OVERSIGHT ON TJC, STATE/FEDERAL LEVELS				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SAJAL K. ROY

Print Name (First, Last)

Sajal Roy — 1/5/26

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Louisiana, ss. County of Calcasieu

I, Sajal Roy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sajal Roy — 1/5/26

Original Signature — **Date**

Subscribed and Sworn to before me this 5th day of January, 2026

Amy E. Donovan

Notary Public Signature

STATE OF LOUISIANA — UNION · JUSTICE · CONFIDENCE

OFFICIAL SEAL
AMY E. DONOVAN
NOTARY ID # 68333
STATE OF LOUISIANA
PARISH OF CALCASIEU
My Commission is for Life

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PHARMA FUSION LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04722

Physical Address 2580 HWY 95, STE 218

City BULLHEAD CITY State LA Zip 86442

Mailing Address (if different from physical address) 518 PUJO STREET

City LAKE CHARLES State LA Zip 70601

Telephone (928) 876-0158 Website WWW.PHARMAFUSIONRX.COM

Licensing Company Email LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First HAROLD Middle EUGENE Last CANNON

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
BLOOMSBURG UNIVERSITY		08/1983-06/1985	
Address	**City**	**State**	**Zip**
400 EAST 2ND STREET	BLOOMSBURG	PA	17815
Diploma/Degree obtained, if any			
BACHELOR'S DEGREE			

School Name		From - To (MM/YY – MM/YY)	
WILLIMSPORT AREA COMMUNITY COLLEGE		08/1981-06/1983	
Address	**City**	**State**	**Zip**
1 COLLEGE AVENUE	WILLIAMSPORT	PA	17701
Diploma/Degree obtained, if any			
ASSOCIATES DEGREE			

School Name		From - To (MM/YY – MM/YY)	
MIFFLINBURG AREA H.S.		09/1977-06/1981	
Address	**City**	**State**	**Zip**
75 MARKET STREET	MIFFLINBURG	PA	17844
Diploma/Degree obtained, if any			
H.S. DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2018-PRESENT	[redacted]			
01/2013-12/2017				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
PHARMA FUSION HOLDINGS, INC.			12/31/2025-PRESENT	
Business Address		**City**	**State**	**Zip**
518 PUJO STREET		LAKE CHARLES	LA	70601
Phone	**Title**			
(337) 761-5397	SHAREHOLDER			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
SOUTH WALTON PHARMACY, LLC			12/2022-PRESENT	
Business Address		**City**	**State**	**Zip**
2050 W COUNTY HWY 30a, M1-106		SANTA ROSA BEACH	FL	32459
Phone	**Title**			
(850) 622-3313	PRESIDENT/SOLE MEMBER			
Description of Duties				
OVERSIGHT OF LLC OPERATIONS				

Business Name			From - To (MM/YY – MM/YY)	
HEC ACCOUNTING			01/1994-PRESENT	
Business Address		**City**	**State**	**Zip**
131 SOUTH MAIN STREET		TAYLOR	PA	18517
Phone	**Title**			
(570) 606-0704	OWNER			
Description of Duties				
PROVIDING TAX & FINANCIAL CONSULTING SERVICES FOR INDIVIDUALS/BUSINESSES				

Business Name			From - To (MM/YY – MM/YY)	
ETHICAL FACTOR RX			10/2019-PRESENT	
Business Address		**City**	**State**	**Zip**
4213 BIRNEY AVENUE, SUITE 4		MOOSIC	PA	18507
Phone	**Title**			
(570) 606-3622	CHIEF FINANCIAL OFFICER			
Description of Duties				
MANAGING OFFICE STAFF/DUTIES & ACCREDITATION PROCEDURES				

Business Name			From - To (MM/YY – MM/YY)	
PROVIDER EXPANDED CONTRACT & SERVICE ACCREDITATION, INC			12/2020-PRESENT	
Business Address		**City**	**State**	**Zip**
7207 RISING SUN AVENUE		PHILADELPHIA	PA	19111
Phone	**Title**			
(570) 331-1691	PRESIDENT			
Description of Duties				
DESIGN & REVIEW OF AUTOMATED PATIENT MANAGEMENT PROGRAMS WHICH INTEGRATE WITH ACCREDITATION AGENCIES & THIRD-PARTY CONTRACTING				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
LUSTRUM MARKETING & ADMINISTRATIVE SERVICES			01/2014-12/31/2019
Business Address	**City**	**State**	**Zip**
223 W 6TH STREET	WEST WYOMING	PA	18644
Phone	**Title**		
(215) 278-9871	PRESIDENT		
Description of Duties			
DEVELOPMENT OF MARKETING STRATEGIES TO ENABLE BUSINESSES TO INCREASE REVENUE & STREAMLINE OR AUTOMATE CLERICAL PROCESSES			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HAROLD E. CANNON

Print Name (First, Last)

Harold E. Cannon — 1-5-2026

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Walton

I, Harold E. Cannon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Harold E. Cannon — 1-5-2026

Original Signature — **Date**

Subscribed and Sworn to before me this 5th day of January.

Tanya Lynn Milby

Notary Public Signature

TANYA LYNN MILBY
Notary Public - State of Florica
Commission # HH 510767
My Comm. Expires Apr 1, 2028
Bonded through National Notary Assn.
(Seal)

Docusign Envelope ID: 3D752877-C469-4A26-95B1-C81F0213835B

ASSIGNMENT OF MEMBERSHIP INTERESTS

THIS ASSIGNMENT OF MEMBERSHIP INTERESTS (this "**Assignment**") is dated as of December 31, 2025 (the "**Effective Date**") , by and between Sajal Roy ("**Assignor**") and Pharma Fusion Holdings, Inc., a Louisiana corporation ("**Assignee**").

W I T N E S S E T H:

WHEREAS, Assignor is the sole member of Pharma Fusion LLC, a Louisiana limited liability company (the "**Company**"), and the record and beneficial owner of 100% of the membership interests therein (the "**Membership Interests**");

WHEREAS, Assignor desires to transfer and assign to Assignee 100% of his Membership Interests (the "**Assigned Interests**"), and Assignee desires to accept the transfer and assignment of the Assigned Interests; and

WHEREAS, pursuant to the terms of this Assignment, Assignor shall transfer and assign to Assignee the Assigned Interests.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor and Assignee hereby agree as follows:

1. **Assignment.** Assignor hereby sells, transfers, conveys, delivers and assigns to Assignee all of Assignor's right, title and interest in and to the Assigned Interests, including all of Assignor's rights as a member of the Company associated with the ownership of Assignor's Assigned Interests, whether specified by applicable law or in the organizational documents of the Company.

2. **Assumption.** Assignee hereby accepts the Assigned Interests and assumes and agrees, from and after the date of this Agreement, promptly and faithfully to keep, fulfill, observe, perform and discharge, as if it was the Assignor, each and every covenant, duty, debt, obligation and liability associated with the ownership of the Assigned Interests arising after the date of this Agreement.

3. **Entire Agreement.** This Assignment, including any exhibits, schedules and other documents referred to or delivered pursuant hereto, contain the entire understanding of the parties with respect to the subject matter hereof and thereof. This Assignment may be amended only by a written instrument duly executed by Assignor and Assignee.

4. **Counterparts.** This Assignment may be executed in multiple counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

5. **Electronic Signatures.** The parties agree that this Assignment and any related documents may be executed and delivered by electronic means, including via facsimile, PDF, or electronic signature platforms (e.g., DocuSign), and such execution shall be deemed valid

and binding as if original signatures were exchanged. Each party agrees that electronically signed documents shall have the same legal effect as manually signed originals.

6. **Governing Law.** This Assignment shall be governed by the laws of the State of Louisiana without regard to conflicts of law principles.

7. **Acknowledgement.** The parties acknowledge and agree that the Effective Date, and not the date of execution of this Assignment, shall control for all financial, accounting, tax, regulatory, and licensing purposes.

[Signatures appear on the following page]

IN WITNESS WHEREOF, the undersigned have executed this Assignment as of the date first set forth above.

ASSIGNOR:

Signed by:
Dr. Sajal Roy
E73C5814DD0740C...

Sajal Roy

ASSIGNEE:

PHARMA FUSION HOLDINGS, INC.

Signed by:
Dr. Sajal Roy
E73C5814DD0740C...

By:
Name: Sajal Roy
Title: Director

4KKK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH PH004422		☐ Other: SPECIALTY

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: South Walton Pharmacy, LLC dba SANTA ROSA PHARMACY

Physical Address: 2050 W COUNTY HWY 30a, M1-106

City: SANTA ROSA BEACH State: FL Zip: 32459

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: (850) 622-3313 Toll Free # (NAC 639.708, NRS 639.23286): (855) 957-6220

Fax: (850) 622-3255 Contact Email: JBERRYBEDELL@PHARMAFUSIONRX.COM

Website: WWW.PHARMAFUSIONRX.COM

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): JOANN E. BERRY-BEDELL, BS.PHARM.

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: NHAN T. NGUYEN, PHARM.D.	NV Pharmacist Registration #: 19172
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.012S, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A - NO HEALTH PROFESSIONAL OWNER	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NOT APPLICABLE

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FLORIDA

Parent Company (if any): PHARMA FUSION HOLDINGS, INC.

Corporation/Organization Name: SOUTH WALTON PHARMACY, LLC

Mailing Address: 518 PUJO STREET

City: LAKE CHARLES State: LA Zip: 70601

Telephone: (377) 761-5397 Email: SROY@PHARMAFUSIONRX.COM

Contact Person Name: SAJAL K. ROY, PHARM.D.

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☒ Yes ☐ No

COMPLETE LIST ACCOMPANIES

Section 7: Partnership

Partnership Name: NOT APPLICABLE

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NOT APPLICABLE

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PIC/PHARMACY MANAGER (title) for SOUTH WALTON PHARMACY, LLC dba SANTA ROSA PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

JOANN E. BERRY-BEDELL, BS.PHARM.

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/13/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, JOANN E. BERRY-BEDELL, BS. PHARM. hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PIC/PHARMACY MANAGER (title) for SOUTH WALTON PHARMACY, LLC dba SANTA ROSA PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of January, 2024

Notary Public

TANYA LYNN MILBY
Notary Public - State of Florida
Commission # HH 510767
My Comm. Expires Apr 1, 2028
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SAJAL K. ROY, PHARM.D.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Sajal Roy

Original signature of Authorized Person (copies or stamps not accepted)

1/13/26

Date

Board Use Only	Date Received: 1/15/26	Amount: $500-Ck 3242

PHARMA FUSION HOLDINGS, INC.
518 Pujo Street
Lake Charles, LA 70601

OWNERSHIP

Sajal K. Roy, Pharm.D.
56.68%
[redacted]

Harold E. Cannon
40.41%
[redacted]

John DeWolf
1.24%
[redacted]

Harpreet Mann
1.04%
[redacted]

Armando Serrano
0.62%
[redacted]

OFFICERS

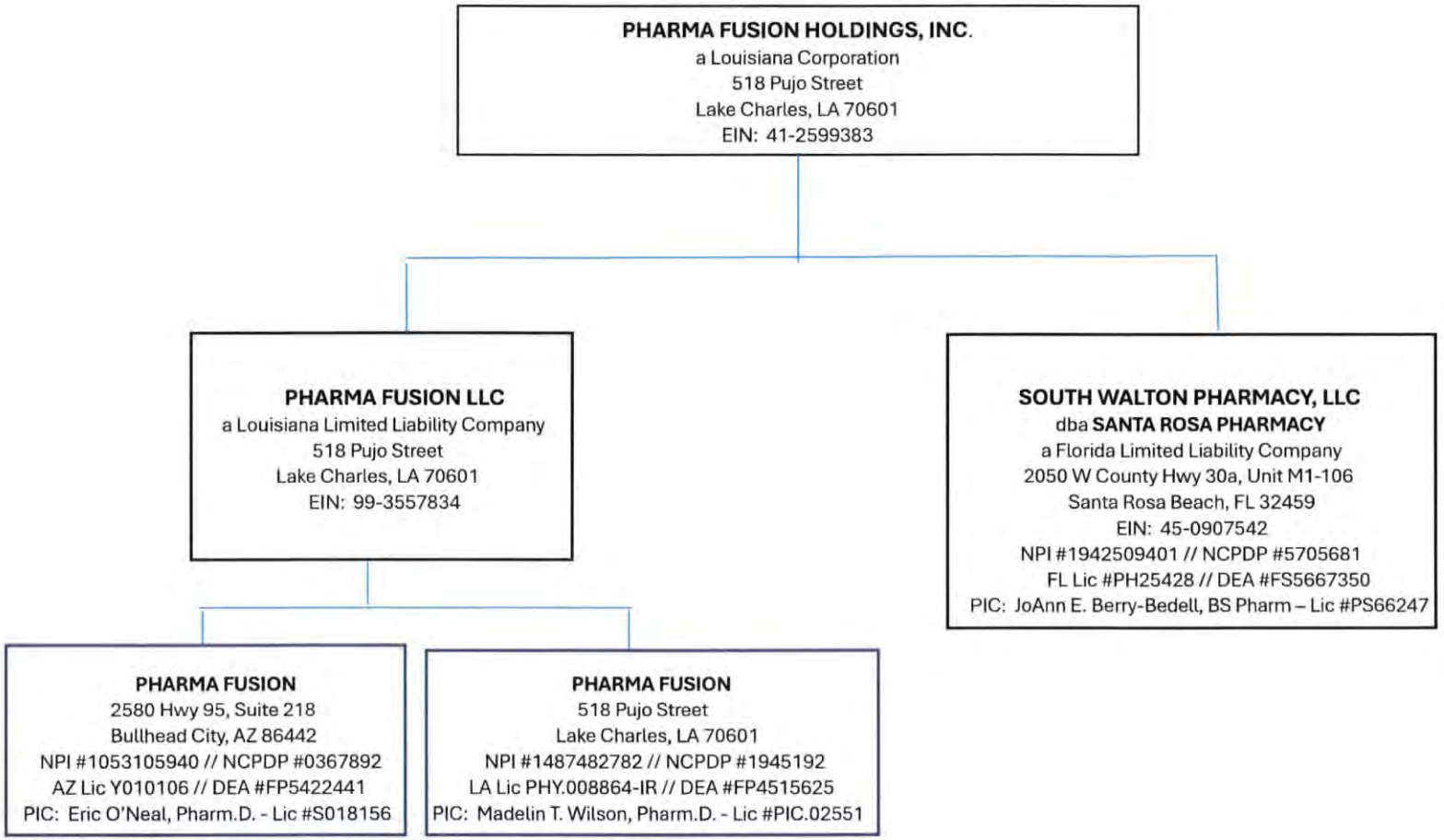
Sajal K. Roy, Pharm.D.,
President/Director
[redacted]

Richard A. Rodrigue, Pharm.D.,
Chief Executive Officer
[redacted]

Caitlin A. Henderson,
Chief Administrative Officer
[redacted]

PHARMA FUSION

ORGANIZATIONAL STRUCTURE



State of Florida
Department of State

I certify from the records of this office that SOUTH WALTON PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on March 18, 2011, effective March 18, 2011.

The document number of this limited liability company is L11000033039.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on January 8, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Thirty-first day of December, 2025

Secretary of State

Tracking Number: 1356711452CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SOUTH WALTON PHARMACY, LLC dba SANTA ROSA PHARMACY

Pharmacy/Wholesaler License # (if applicable) PH0442

Physical Address 2050 W COUNTY HWY 30a, M1-106

City SANTA ROSA BEACH State FL Zip 32459

Mailing Address (if different from physical address) SAME

City State Zip

Telephone (850) 622-3313 Website WWW.PHARMAFUSIONRX.COM

Licensing Company Email LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First JOANN Middle ELEANORE Last BERRY-BEDELL

Alias(es, nicknames, name changes, etc.) Jodie, Wilczewski, Berry

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted]

City [redacted] Stat [redacted] Z [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. Louis College of Pharmacy (University of Health Sciences & Pharmacy)		08/1985-05/1990	
Address	**City**	**State**	**Zip**
1 Pharmacy Place	St. Louis	MO	63110
Diploma/Degree obtained, if any			
Bachelor of Science-Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Nazareth Academy		08/1981-06/1985	
Address	**City**	**State**	**Zip**
1209 Ogden Avenue	LaGrange Park	IL	60526
Diploma/Degree obtained, if any			
High school graduate			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2023-current	[redacted]			
08/1995-10-2023				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
South Walton Pharmacy dba Santa Rosa Pharmacy			02/2024-current	
Business Address		**City**	**State**	**Zip**
2050 W. County Hwy 30A		Santa Rosa Beach	FL	32459
Phone	**Title**		**Number of Employed Hours**	
850-622-3313	Pharmacy Manager		1760	
Description of Duties				
Oversee daily pharmacy operations of the pharmacy including compliance, regulatory, ordering & inventory, facility, staff management, safe processing of prescriptions,& clinical patient management.				

Business Name			From - To (MM/YY – MM/YY)	
Coram Specialty Infusion Services (CLOSED)			09/2023-02/2024	
Business Address		**City**	**State**	**Zip**
3439 N. 12th Ave		Pensacola	FL	32503
Phone	**Title**		**Number of Employed Hours**	
	Pharmacy Manager		2560	
Description of Duties				
oversee daily operations of a sterile compounding pharmacy including safe processing of prescriptions, hiring, training, compliance, cleanroom operations, clinical patient management				

Business Name			From - To (MM/YY – MM/YY)	
Coram Specialty Infusion Services (Remote)			10/2018-09/2023	
Business Address		**City**	**State**	**Zip**
1 CVS Drive		Woonsocket	RI	02895
Phone	**Title**		**Number of Employed Hours**	
1-800-746-7287	Pharmacist Advisor		10400	
Description of Duties				
various responsibilities including policy & procedure review, corporate compliance support, onsite pharmacist training & training, UAT testing, database support and national clinical support.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, JOANN E. BERRY-BEDELL, BS.PHARM., **certify that as the designated representative for**

SOUTH WALTON PHARMACY, LLC dba SANTA ROSA PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JOANN E. BERRY-BEDELL, BS.PHARM.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JOANN E. BERRY-BEDELL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of WALTON

I, JoAnn E. Berry-Bedell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/5/26

Date

Subscribed and Sworn to before me this 5TH day of January.

Notary Public Signature

ANYA LYNN MILBY
Public - State of Florida
mission # HH 310767
mm. Expires Apr 1, 2028
through National Notary Assn

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 18374
Insp # 189515

NAME	PERMIT NUMBER	DATE OF INSPECTION
SOUTH WALTON PHARMACY LLC	25428	09/17/2024
DOING BUSINESS AS		
SANTA ROSA PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
2050 West COUNTY HWY 30A UNIT M1-106	850-622-3313	
CITY	**COUNTY**	**STATE/ZIP**
SANTA ROSA BEACH	WALTON	FL/32459

Additional Information

Business Operation Hours

M-T-W-TH-F N	Sunday N
Sunday Hours Closed	Monday Y
Monday Hours 8:30 AM TO 5 PM	Tuesday Y
Tuesday Hours 8:30 AM TO 5 PM	Wednesday Y
Wednesday Hours 8:30 AM TO 5 PM	Thursday Y
Thursday Hours 8:30 AM TO 5 PM	Friday Y
Friday Hours 8:30 AM TO 5 PM	Saturday Y
Saturday Hours closed	

Registered Pharmacist / Intern / Tech

License # PS 62301	Licensee Name Amanda Bercey
License Type Registered Pharmacists	
License # RPT 13476	Licensee Name Tanya Milby
License Type Pharmacy Tech	
License # PS 55984	Licensee Name Nhan Nguyen
License Type Registered Pharmacists	
License # PS 53104	Licensee Name Tarina Asha Jain Coburn
License Type Registered Pharmacists	
License # PS 65269	Licensee Name Rachel Anne Blythe
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FS2663791	

License Relations

Pharmacy Affiliate

CANNON, HAROLD E	License #

RX DPT MGR/COR/POR

BERCEY, AMANDA	License # 62301

Special Sterile Compounding

SOUTH WALTON PHARMACY, LLC	License # 34007

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes
"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.]	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a),.F.A.C.]	Yes
Pharmacists, technicians, and Interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.] *none*	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	Yes
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.]	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.] *none*	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.] *none*	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11]	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	Yes
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(a), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.] *none*	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.] *none*	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

INV359 - Community Requirements

Insp # 189515

SOUTH WALTON PHARMACY LLC

File # 18374

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes
Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CHILDERS, MARVEL

Date:9/17/2024

Representative:

Amanda Bercey

Date:9/17/2024

Your license number is PH 25428.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
DECEMBER 27, 2024	**PH 25428**	**146858**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Schedule II & III
Community Pharmacy

EXPIRATION DATE: **FEBRUARY 28, 2027**

SOUTH WALTON PHARMACY LLC
SANTA ROSA PHARMACY
2050 WEST COUNTY HWY 30A
UNIT M1-106
SANTA ROSA BEACH, FL - 32459

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
DECEMBER 27, 2024	**PH 25428**	**146858**

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

SOUTH WALTON
PHARMACY LLC
SANTA ROSA

Expiration Date: **FEBRUARY 28, 2027**

REGISTRANT SIGNATURE

Department of Health

SOUTH WALTON PHARMACY LLC

SANTA ROSA PHARMACY

License Number: PH25428

Data As Of 1/8/2026

Profession	Pharmacy
License	PH25428
License Status	Clear/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2027
License Original Issue Date	04/25/2011
Address of Record	2050 West COUNTY HWY 30A UNIT M1-106 SANTA ROSA BEACH, FL 32459
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
BERRY-BEDELL, JOANN ELEANORE	RX DPT MGR/COR/POR	PHARMACIST	66247	03/01/2025
CANNON, HAROLD E	PHARMACY AFFILIATE	PHARMACY AFFILIATE		12/30/2022

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: South Walton Pharmacy, LLC dba SANTA ROSA PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04422

Physical Address: 2050 W COUNTY HWY 30a, M1-106

City: SANTA ROSA BEACH State: FL Zip: 32459

Mailing Address (if different from physical address): 518 PUJO STREET

City: LAKE CHARLES State: LA Zip: 70601

Telephone: (337) 761-5397 Website: WWW.PHARMAFUSIONRX.COM

Licensing Company Email: LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First: John Middle: Thomas Martin Last: DeWolf

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✗

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✗
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✗

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
St. Charles East HS			1996 – 2000	
Address		City	State	Zip
1020 Dunham Rd.		St. Charles	IL	60174
Diploma/Degree obtained, if any				
Diploma				

School Name			From - To (MM/YY – MM/YY)	
Triton College			2007 – 2009	
Address		City	State	Zip
2000 5th Ave		River Grove	IL	60171
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2011 – current	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Pharma Fusion			From - To (MM/YY – MM/YY): 06/25 - Current	
Business Address: 518 Pujo St.	City: Lake Charles		State: LA	Zip: 70601
Phone: 337-761-5397	Title: VP of Bleeding Disorders			
Description of Duties: Manage sales team for entire country				

Business Name: Care Partners			From - To (MM/YY – MM/YY): 06/22 - 06/25	
Business Address: 326 Peterson ~~Rd~~ Rd.	City: Libertyville		State: IL	Zip: 60048
Phone: 866-852-0202	Title: Sales Rep.			
Description of Duties: Manage patients on service, sell services of the pharmacy.				

Business Name: InfuCare			From - To (MM/YY – MM/YY): 10/2018 - 06/23	
Business Address: 2400 Veterans Memorial Blvd	City: Kenner		State: LA	Zip: 70062
Phone: 877-327-8881	Title: Director			
Description of Duties: Management of Sales Team, sell our services to patients.				

Business Name: Affinity Biotech (Diplomat)			From - To (MM/YY – MM/YY): 05/09 - 09/18	
Business Address: 4100 Saginaw St.	City: Flint		State: MI	Zip: 48507
Phone: 877-977-9118	Title: Sales Rep			
Description of Duties: Work w/ chapters + Mfg's, sell our services to patients				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John DeWolf

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/5/26

Date

Please have this section completed in the presence of a Notary Public.

State of LOUISIANA, ss. ~~County~~ PARISH of ST. TAMMANY

I, John DeWolf, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/26

Date

Subscribed and Sworn to before me this 6 day of January.

Notary Public Signature Scott Ruel #27078

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: South Walton Pharmacy, LLC dba SANTA ROSA PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04422

Physical Address: 2050 W COUNTY HWY 30a, M1-106

City: SANTA ROSA BEACH State: FL Zip: 32459

Mailing Address (if different from physical address): 518 PUJO STREET

City: LAKE CHARLES State: LA Zip: 70601

Telephone: (337) 761-5397 Website: WWW.PHARMAFUSIONRX.COM

Licensing Company Email: LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First: Harpreet Middle: Singh Last: Maan

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
California State University, Chico			04/02 – 12/06	
Address: 400 W. 1st	City: Chico	State: CA	Zip: 95929	
Diploma/Degree obtained, if any: Business Administration Degree				
School Name: Yuba City High School			From - To (MM/YY – MM/YY): 01/98 – 01/02	
Address: 850 B St.	City: Yuba City	State: CA	Zip: 95991	
Diploma/Degree obtained, if any: High School diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/25 – 01/26	[redacted]			
01/24 – 03/25				
05/21 – 01/24				
01/19 – 05/21				
08/17 – 01/19				
09/09 – 08/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Pharma Fusion, LLC			From - To (MM/YY – MM/YY): 01/26 - 01/26	
Business Address: 518 Pujo St.	City: Lake Charles	State: LA	Zip: 70601	
Phone: 337-761-5397	Title: Vice President of Strategy			
Description of Duties: Develope any and all strategy to foster future growth				

Business Name: Santa Rosa Pharmacy			From - To (MM/YY – MM/YY): 02/24 - 12/25	
Business Address: 2050 W. County Hwy 30A Ste 106	City: Santa Rosa Beach	State: FL	Zip: 32459	
Phone: 850-622-3313	Title: Vice President of Strategy			
Description of Duties: Develope any and all strategy to foster future growth				

Business Name: Octapharma			From - To (MM/YY – MM/YY): 01/19 - 01/24	
Business Address: 117 W. Century Rd.	City: Paramus	State: NJ	Zip: 07652	
Phone: 201-604-1130	Title: Coagulation Sales Specialist			
Description of Duties: Mgmt of sales in AL, WA, OR, N-CA & ID				

Business Name: Drug Co Pharmacy			From - To (MM/YY – MM/YY): 01/17 - 01/19	
Business Address: 107 Smith Church Rd	City: Roanoke Rapids	State: NC	Zip: 27870	
Phone:	Title: Western Sales Manager			
Description of Duties: Responsible for whole Western 1/2 of USA Sales				

Business Name: Hemophiliac Support Systems			From - To (MM/YY – MM/YY): 01/16 - 01/17	
Business Address: 5721 Lincoln Ave.	City: Cypress	State: CA	Zip: 90630	
Phone: 888-439-4366	Title: Sales Manager			
Description of Duties: Mgmt of all sales for company				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Guidant Alliance Healthcare Services			11/07 - 01/16
Business Address	City	State	Zip
27111 Aliso Creek Rd Ste 185a	Aliso Viejo	CA	92656
Phone	Title		
949-496-4106	District Manager		
Description of Duties			
Mgmt of All Sales			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Harpreet, Maan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Walton

I, Harpreet, Maan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Harpreet Maan

Original Signature

1-5-2025

Date

Subscribed and Sworn to before me this 5th day of January 2026.

Tanya Lynn Milby

Notary Public Signature

TANYA LYNN MILBY
Notary Public - State of Florida
Commission # HH 510767
My Comm. Expires Apr 1, 2028
Bonded through National Notary Assn.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: South Walton Pharmacy, LLC dba SANTA ROSA PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04422

Physical Address: 2050 W COUNTY HWY 30a, M1-106

City: SANTA ROSA BEACH State: FL Zip: 32459

Mailing Address (if different from physical address): 518 PUJO STREET

City: LAKE CHARLES State: LA Zip: 70601

Telephone: (850) 622-3313 Website: WWW.PHARMAFUSIONRX.COM

Licensing Company Email: LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First: SAJAL Middle: K Last: ROY

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE SCIENCES		1998-2004	
Address	**City**	**State**	**Zip**
600 S 43 STREET	PHILADELPHIA	PA	19104
Diploma/Degree obtained, if any			
DOCTOR OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
WISSAHICKON HIGH SCHOOL		1994-1998	
Address	**City**	**State**	**Zip**
531 HOUSTON ROAD	AMBLER	PA	19002
Diploma/Degree obtained, if any			
H. S. DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2018-PRESENT	[redacted]			
03/2016-07/2018				
02/2012-02/2016				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
PHARMA FUSION HOLDINGS, INC.			12/31/2025-PRESENT
Business Address	**City**	**State**	**Zip**
518 PUJO STREET	LAKE CHARLES	LA	70601
Phone	**Title**		
(337) 761-5397	PRESIDENT/DIRECTOR		
Description of Duties			
RESPONSIBLE FOR OVERSIGHT OF ALL COMPANY/PHARMACY OPERATIONS			

Business Name			From - To (MM/YY – MM/YY)
PHARMA FUSION LLC			06/2024-PRESENT
Business Address	**City**	**State**	**Zip**
518 PUJO STREET	LAKE CHARLES	LA	70601
Phone	**Title**		
(337) 761-5397	CEO/PIC		
Description of Duties			
OVERSIGHT OF ALL COMPANY OPERATIONS & DISPENSING ACTIVITIES			

Business Name			From - To (MM/YY – MM/YY)
INFUCARE RX INC/FACTOR ONE SOURCE/FAST PHARMACY			01/2019-01/2021
Business Address	**City**	**State**	**Zip**
2400 VETERANS MEMORIAL BLVD, STE 480	KENNER	LA	70062
Phone	**Title**		
(877) 327-8881	OWNER/VP OF OPERATIONS		
Description of Duties			
RESP FOR OVERSIGHT OF ALL OPERATIONS/DISPENSING ACTIVITIES			

Business Name			From - To (MM/YY – MM/YY)
FACTOR ONE SOURCE/FAST PHARMACY			03/2014-12/2018
Business Address	**City**	**State**	**Zip**
300 GLEN STREET	CUMBERLAND	MD	21502
Phone	**Title**		
(844) 733-6779	CEO/OWNER		
Description of Duties			
OVERSIGHT OF ALL COMPANY OPERATIONS/ DISPENSING ACTIVITIES			

Business Name			From - To (MM/YY – MM/YY)
WESTERN MARYLAND HEALTH SYSTEM (WMHS)			2014-2015
Business Address	**City**	**State**	**Zip**
12500 WILLOWBROOK ROAD	CUMBERLAND	MD	21502
Phone	**Title**		
(240) 964-1399	EXEC DIR OF CLINICS & PRACTICES/PHARMACY SERVICES		
Description of Duties			
OVERSIGHT & DEVELOPMENT OF 20 PRIMARY, URGENT & SPECIALTY CARE OFFICES FORMATION OF ACO WITH 10,000 LIVES			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
WESTERN MARYLAND HEALTH SYSTEMS (WMHS)			2012-2014	
Business Address		City	State	Zip
12500 WILLOWBROOK ROAD		CUMBERLAND	MD	21502
Phone	Title			
(240) 964-1399	DIR OF PHARMACY SERVICES/DIRECTOR OF QUALITY/COMPLIANCE			
Description of Duties				
OVERSIGHT INPATIENT & CLINICAL PHARM. PROGRAMS/OUTPATIENT PHARMACY SVCS. DEVEL/MONITOR QUALITY INITIATIVES; COMPLIANCE OVERSIGHT ON TJC, STATE/FEDERAL LEVELS				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SAJAL K. ROY

Print Name (First, Last)

Sajal Roy — 1/5/26

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Louisiana, ss. County of Calcasieu

I, Sajal Roy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sajal Roy — 1/5/26

Original Signature — **Date**

Subscribed and Sworn to before me this 5th day of January, 2026

Amy E. Donovan

Notary Public Signature

OFFICIAL SEAL
AMY E. DONOVAN
NOTARY ID # 68333
STATE OF LOUISIANA
PARISH OF CALCASIEU
My Commission is for Life

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: South Walton Pharmacy, LLC dba SANTA ROSA PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04422

Physical Address: 2050 W COUNTY HWY 30a, M1-106

City: SANTA ROSA BEACH State: FL Zip: 32459

Mailing Address (if different from physical address): 618 PUJO STREET

City: LAKE CHARLES State: LA Zip: 70601

Telephone: (337) 761-5397 Website: WWW.PHARMAFUSIONRX.COM

Licensing Company Email: LICENSING@PHARMAFUSIONRX.COM

Section 2: Personal Information

First: HAROLD Middle: EUGENE Last: CANNON

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
BLOOMSBURG UNIVERSITY		08/1983-06/1985	
Address	City	State	Zip
400 EAST 2ND STREET	BLOOMSBURG	PA	17815
Diploma/Degree obtained, if any			
BACHELOR'S DEGREE			

School Name		From - To (MM/YY – MM/YY)	
WILLIMSPORT AREA COMMUNITY COLLEGE		08/1981-06/1983	
Address	City	State	Zip
1 COLLEGE AVENUE	WILLIAMSPORT	PA	17701
Diploma/Degree obtained, if any			
ASSOCIATES DEGREE			

School Name		From - To (MM/YY – MM/YY)	
MIFFLINBURG AREA H.S.		09/1977-06/1981	
Address	City	State	Zip
75 MARKET STREET	MIFFLINBURG	PA	17844
Diploma/Degree obtained, if any			
H.S. DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2018-PRESENT	[redacted]			
01/2013-12/2017				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
PHARMA FUSION HOLDINGS, INC.			12/31/2025-PRESENT
Business Address	**City**	**State**	**Zip**
518 PUJO STREET	LAKE CHARLES	LA	70601
Phone	**Title**		
(337) 761-5397	SHAREHOLDER		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
SOUTH WALTON PHARMACY, LLC			12/2022-PRESENT
Business Address	**City**	**State**	**Zip**
2050 W COUNTY HWY 30a, M1-106	SANTA ROSA BEACH	FL	32459
Phone	**Title**		
(850) 622-3313	PRESIDENT/SOLE MEMBER		
Description of Duties			
OVERSIGHT OF LLC OPERATIONS			

Business Name			From - To (MM/YY – MM/YY)
HEC ACCOUNTING			01/1994-PRESENT
Business Address	**City**	**State**	**Zip**
131 SOUTH MAIN STREET	TAYLOR	PA	18517
Phone	**Title**		
(570) 606-0704	OWNER		
Description of Duties			
PROVIDING TAX & FINANCIAL CONSULTING SERVICES FOR INDIVIDUALS/BUSINESSES			

Business Name			From - To (MM/YY – MM/YY)
ETHICAL FACTOR RX			10/2019-PRESENT
Business Address	**City**	**State**	**Zip**
4213 BIRNEY AVENUE, SUITE 4	MOOSIC	PA	18507
Phone	**Title**		
(570) 606-3622	CHIEF FINANCIAL OFFICER		
Description of Duties			
MANAGING OFFICE STAFF/DUTIES AND ACCREDITATION PROCEDURES			

Business Name			From - To (MM/YY – MM/YY)
PROVIDER EXPANDED CONTRACT & SERVICE ACCREDITATION, INC			12/2020-PRESENT
Business Address	**City**	**State**	**Zip**
7207 RISING SUN AVENUE	PHILADELPHIA	PA	19111
Phone	**Title**		
(570) 331-1691	PRESIDENT		
Description of Duties			
DESIGN & REVIEW OF AUTOMATED PATIENT MANAGEMENT PROGRAMS WHICH INTEGRATE WITH ACCREDITATION AGENCIES & THIRD-PARTY CONTRACTING			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
LUSTRUM MARKETING & ADMINISTRATIVE SERVICES			01/2014-12/31/2019
Business Address	**City**	**State**	**Zip**
223 W 6TH STREET	WEST WYOMING	PA	18644
Phone	**Title**		
(215) 278-9871	PRESIDENT		
Description of Duties			
DEVELOPMENT OF MARKETING STRATEGIES TO ENABLE BUSINESSES TO INCREASE REVENUE & STREAMLINE OR AUTOMATE CLERICAL PROCESSES			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HAROLD E. CANNON

Print Name (First, Last)

Harold E. Cannon — 1-5-2026

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Walton

I, Harold E. Cannon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Harold E. Cannon — 1-5-2026

Original Signature — **Date**

Subscribed and Sworn to before me this 5th day of January.

Tanya Lynn Milby

Notary Public Signature

TANYA LYNN MILBY
Notary Public - State of Florida
Commission # HH 510767
My Comm. Expires Apr 1, 2028
Bonded through National Notary Assn.
(Seal)

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ANNUAL DISCIPLINE CASES Reporting Period: January 2026			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
CVS is responsible for the acts of its employees who made an error in a prescription that results in negative outcome to the patient.	Yes	N/A	Respondent fined $10,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent KA made an error in a prescription that resulted in negative outcome to the patient.	Yes	Respondent's Certificate of Registration No. 19679 is suspended for a period of one year. The suspension is stayed, and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; 2) Respondent assessed $500 in attorney's fees and costs; and 3) Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against him.	N/A
Respondent RA allowed non-practitioners to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.	No	Respondent's Certificate of Registration No. CS30228 is suspended for a period of one year. The suspension is stayed, and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order is a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against her while on probation.	N/A

Respondent CL prescribed dangerous drugs to patients with whom Respondent had not established a bona fide therapeutic relationship and failed to timely report disciplinary action.	No	Respondent's Certificate of Registration No. CS31815 is suspended for a period of one year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order as a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
Respondent GO dispensed controlled substances without a valid dispensing practitioner registration and failed to review PMP.	No	Respondent's Certificate of Registration No. CS35044 is suspended for a period of one year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order as a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
As pharmacy/pharmacy owner, Costco Pharmacy is responsible for the acts of its employees who made an error in a prescription.	Yes	N/A	Respondent fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent CV made an error in a prescription.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

Respondent DY allowed a non-practitioner to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.	No	Respondent's Certificate of Registration No. CS06454 is placed on probation for one year subject to the following conditions: 1) Respondent shall accept the Stipulation and Order is a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
The Nevada BOP took reciprocal disciplinary action on AW's Certificate of Registration No. 22724 based upon disciplinary action by the Arizona Board of Pharmacy for diversion.	No	Respondent's Certificate of Registration No. 22724 is placed on probation until October 29, 2029, and Respondent shall fully comply with the Arizona BOP Consent Order in Case No. 24-0394. Respondent fined $1,000 for the violations.	N/A
As pharmacy/pharmacy owner, SP is responsible for the acts of its employees who mailed dangerous drugs in California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail pharmacy license in those states.	No	N/A	Respondent accepts the Stipulation as a public reprimand. Respondent has forfeited License No. PH03880 when they failed to renew their license on November 1, 2020. Respondent fined $5,000 for the violations and assessed $1,000 in attorney's fees and costs.
As managing pharmacist during the time of the events, Respondent TA was aware and is responsible for the acts of its employees who mailed dangerous drugs in California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail pharmacy license in those states.	No	Respondent's Certificate of Registration No. 19070 is revoked. The revocation is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs; 3) Respondent shall complete two additional hours of continuing education on duties of a managing pharmacist; and 4) As a condition or probation, Respondent shall not engage in any conduct for which disciplinary action may be imposed pursuant to the provisions.	N/A

Respondent RM dispensed dangerous drugs without a dispensing registration; held for sale an adulterated drug; failed to produce complete and accurate records of all dangerous drugs dispensed to patients; failed to store and/or possess dangerous drugs from patients and employees that were not in stock containers properly labeled and procured from a manufacturer, wholesaler or pharmacy; and did not acquire the dangerous drugs from patients and employees pursuant to a prescription written by himself or another practitioner, and/or were not dispensed to Respondent by a pharmacy or dispensing practitioner.	No	Respondent accepts the Stipulation as a public reprimand. Respondent fined $5,000 for the violations and assessed $500 in attorney's fees and costs.	N/A
Respondent EW failed to disclose on his 2022 controlled substance application renewal that he had been subject to disciplinary action before numerous state boards of medicine.	No	Respondent fined $1,000 for the violations.	N/A
As pharmacy/pharmacy owner, WP is responsible for the acts of its employees who made an error in a prescription that resulted in a negative outcome to the patient.	Yes	N/A	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs. Respondent will ensure all pharmacies in Nevada that use automated filling cells required pharmacists to review the SOPs for filling automated cells with medications from stock bottles within 60 days of the effective date of the Order. In addition, Walgreens #8342 will cease using the Yuyama EV-1 automated filling cells as of January 31, 2026.

As managing pharmacist during the time of the events, Respondent DW is responsible for the acts of its employees at Partell Pharmacy who dispensed invalid “Emergency Kits” or “COVID Kits” for which the drugs in each kit were not identified on the prescription, and they would substitute Budesonide in the “COVID Kit” with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner.	No	Respondent accepts this Stipulation as a public reprimand; Respondent’s Certificate of Registration No. 13635 has been forfeited since he failed to renew it on November 1, 2025; Respondent shall pay a fine of $5,000 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
Respondent SS was arrested for a DUI and was under the influence of alcohol and Diazepam, a controlled substance. He did not have a valid U.S. prescription as he obtained the medication from a prescription issued by a licensed physician in Thailand. Respondent was disciplined by the California BOP where the Nevada BOP took reciprocal action.	No	Respondent accepts the Stipulation as a public reprimand; and assessed $500 in attorney’s fees and costs.	N/A

5A

FILED
NOV 1 1 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MATTHEW E. APEL, MD,
Certificate of Registration Nos.
CS24505 and PD00589,

and

THOMAS UMBACH, MD,
Certificate of Registration Nos.
CS16064 and PD00512

Respondents.

CASE NOS. 24-044-PD-A-S
24-044-PD-B-S

FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Matthew E. Apel MD (Apel), held Certificate of Registration Nos. CS24505 and PD00589, Respondent Thomas Umbach, MD (Umbach), held Certificate of Registration Nos. CS16064 and PD00512, all issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 28, 2023, an inspection of Apel's and Umbach's practice at Blossom Bariatric, located at 7385 S. Pecos Road – Ste 101 in Las Vegas, revealed numerous violations of law related to controlled substances.

3. Apel failed to indicate on the biennial inventory if the count was taken either as of the opening or as of the close of business, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), NRS 453.246, NRS 453.326(1)(a) and NAC 453.475.

4. Apel and Umbach failed to make and/or maintain acquisition and distribution records of tramadol, a schedule IV substance, transfers from Umbach to Apel, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(a)(2)(iv) and (vii), NRS 453.246 and NRS 453.326(1)(a).

5. Apel failed to record the address of the patient on tramadol dispensing records, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(c), NRS 453.246, NRS 453.326(1)(a) and NAC 453.410(1)(b)(1).

6. Umbach failed to design and operate a system to disclose suspicious orders of controlled substances, in violation of 21 U.S.C. § 832(a), 21 CFR § 1301.74(b), NRS 453.246 and NRS 453.326(1)(a).

7. Umbach failed to register with the Drug Enforcement Administration as a distributor after distributing more than five percent of the total number of dosage units of all controlled substances distributed and dispensed during the same calendar year, in violation of 21 U.S.C. § 822(a) and 21 CFR § 1307.11(b).

8. On or about January 17, 2024, Apel submitted DEA Form 106 documentation and together with a NRS 453.568 Report to the Board reporting the loss of 765 tramadol 50mg tablets resulting from Respondents' failure to provide effective controls and procedures to guard against the theft and diversion of controlled substances and to ensure all drugs were account for, in violation of 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b).

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APPLICABLE LAW

9. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3); NAC 639.7445.

10. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Federal and State Law - Failure to Maintain Security of Controlled Substances

14. By their actions and/or omissions as alleged in paragraph 8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT TWO

Violations of Federal and State Law - Recordkeeping

15. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a), 21 U.S.C. § 832(a), 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), 21 CFR § 1307.11(b), 21 CFR § 1304.22(a)(2)(iv) and (vii), 21 CFR § 1304.22(c), 21 CFR § 1301.74(b), NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1)(b)(1) and NAC 453.475, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

16. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have performed their duties as the holders of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(4).

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COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these Respondents.

Signed this 17th day of NOVEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW E. APEL, MD,** **Certificate of Registration Nos.** **CS24505 and PD00589,** **Respondent.**	**Case No. 24-044-PD-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of November 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW E. APEL, MD,** **Certificate of Registration Nos.** **CS24505 and PD00589,** **Respondent.**	**Case No. 24-044-DS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Matthew E. Apel, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of November 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Matthew Apel
c/o John Snow, Esq
201 S Main St, Suite 1800
Salt Lake City, UT 84111

Matthew Apel
c/o John Snow, Esq.
50 W Liberty St, Suite 750
Reno, NV 89501

Matthew Apel
c/o Janet I. Jenson, Esq.
PO Box 27727
Salt Lake City, UT 84127

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **BLOSSOM BARIATRIC,** **License No. DS00251-CS,** **MATTHEW E. APEL, MD,** **Certificate of Registration Nos.** **CS24505 and PD00589, and** **THOMAS UMBACH, MD,** **Certificate of Registration Nos.** **CS16064 and PD00512** **Respondents.**	**CASE NOS. 24-044-DS-S** **24-044-PD-A-S** **24-044-PD-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Matthew E. Apel MD (Apel), held Certificate of Registration Nos. CS24505 and PD00589, Respondent Thomas Umbach, MD (Umbach), held Certificate of Registration Nos. CS16064 and PD00512, all issued by the Board, and Respondent Blossom Bariatric, License No. DS00251-CS, was licensed by the Board.

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FACTUAL ALLEGATIONS

2. On or about December 28, 2023, an inspection of Apel's and Umbach's practice at Blossom Bariatric revealed numerous violations of law related to controlled substances.

3. Apel failed to indicate on the biennial inventory if the count was taken either as of the opening or as of the close of business, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), NRS 453.246, NRS 453.326(1)(a) and NAC 453.475.

4. Apel and Umbach failed to make and/or maintain acquisition and distribution records of tramadol, a schedule IV substance, transfers from Umbach to Apel, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(a)(2)(iv) and (vii), NRS 453.246 and NRS 453.326(1)(a).

5. Apel failed to record the address of the patient on tramadol dispensing records, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(c), NRS 453.246, NRS 453.326(1)(a) and NAC 453.410(1)(b)(1).

6. Umbach failed to design and operate a system to disclose suspicious orders of controlled substances, in violation of 21 U.S.C. § 832(a), 21 CFR § 1301.74(b), NRS 453.246 and NRS 453.326(1)(a).

7. Umbach failed to register with the Drug Enforcement Administration as a distributor after distributing more than five percent of the total number of dosage units of all controlled substances distributed and dispensed during the same calendar year, in violation of 21 U.S.C. § 822(a) and 21 CFR § 1307.11(b).

8. On or about January 17, 2024, Apel submitted DEA Form 106 documentation and together with a NRS 453.568 Report to the Board reporting the loss of 765 tramadol 50mg tablets resulting from Respondents' failure to provide effective controls and procedures to guard against the theft and diversion of controlled substances and to ensure all drugs were account for, in violation of 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b).

APPLICABLE LAW

9. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3); NAC 639.7445.

10. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Federal and State Law - Failure to Maintain Security of Controlled Substances

14. By their actions and/or omissions as alleged in paragraph 8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT TWO

Violations of Federal and State Law - Recordkeeping

15. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a), 21 U.S.C. § 832(a), 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), 21 CFR § 1307.11(b), 21 CFR § 1304.22(a)(2)(iv) and (vii), 21 CFR § 1304.22(c), 21 CFR § 1301.74(b), NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1)(b)(1) and NAC 453.475, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

16. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have performed their duties as the holders of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(4).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these Respondents.

Signed this 5th day of September 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW E. APEL, MD,** **Certificate of Registration Nos.** **CS24505 and PD00589,** **Respondent.**	**Case No. 24-044-PD-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 5th day of SEPTEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW E. APEL, MD,** **Certificate of Registration Nos.** **CS24505 and PD00589,** **Respondent.**	**Case No. 24-044-DS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Matthew E. Apel, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Blossom Bariatric
7385 S Pecos Rd #101
Las Vegas, NV 89120

Matthew Apel
[redacted]
Las Vegas, NV [redacted]

Matthew Apel
3235 E Warm Springs Rd Suite #110
Las Vegas, NV 89120

Thomas Umbach
[redacted]
Henderson, NV [redacted]

Thomas Umbach
3235 E Warm Springs Rd Suite #100
Las Vegas, NV 89120

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **vs.** **MATTHEW E. APEL, M.D., Certificate of Registration Nos. CS24505 and PD00589, and** **THOMAS UMBACH, M.D., Certificate of Registration Nos. CS16064 and PD00512,** **Respondents.**	**Case No. 24-044-PD-A-S** **24-044-PD-B-S** **ANSWER AND NOTICE OF DEFENSE TO FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

Respondents, above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declare:

1. Dr. Umbach and Dr. Apel are bariatric surgeons who perform hundreds of surgeries every year on morbidly obese patients. Their clinic is Blossom Bariatrics in Las Vegas. Dr. Apel and Dr. Umbach are licensed as "dispensing practitioners" pursuant to the Nevada Administrative Code §§ 639.742 through 639.745.

2. A large majority of the patients of Blossom Bariatrics are from out-of-state. They typically fly in to Las Vegas from all over the country and stay in hotels for the few days that their surgeries require. On the first day, the patients go to Blossom to have preparatory medical work done. This includes testing their blood pressure, having blood work, taking cardiology exams to determine if their hearts are healthy enough for surgery, and getting an endoscopy.

They talk with the staff and the doctors about what to expect, and if they pass all their tests, they are scheduled for surgery the next day at an ambulatory surgical center.

3. In an effort to provide the best care for their patients, Dr. Umbach opened a small facility at Blossom and registered himself and Dr. Apel as "dispensing practitioners." They used the facility for one purpose only which was to provide one drug – tramadol – to their patients for use after their surgery the next day.[1] Each patient received a single bottle of tramadol containing 15 pills and each patient was instructed by the doctor or staff to take one pill every 4 to 6 hours after surgery for pain in doses of 50 milligrams with a maximum of 300 milligrams per day, thus allowing the patient to treat pain for about 2 days after surgery. No patient was ever given more than one bottle, or more than 15 pills.

4. Dr. Umbach wanted to provide the tramadol directly to the patients because it was difficult for most of them to find a pharmacy, given that they were typically from out-of-town and did not know where a pharmacy was, and they had no relationship with any local pharmacy. Also, the patients needed the tramadol for their surgery the next morning, and not every pharmacy had tramadol on hand when patients showed up with their prescription. Dr. Umbach believed that, by making tramadol available at the clinic, he was providing them the best and most convenient care and helping them prepare for their surgery.

5. Therefore, Drs. Apel and Umbach registered as "dispensing practitioners" and used their onsite drug facility for Blossom's patients only. Blossom ordered its one drug – tramadol – from Quality Care Partners ("QCP"), a legitimate pharmaceutical supplier. Blossom operated its practitioner-dispensing inhouse facility for five years, and the Nevada Pharmacy

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[1] Drs. Umbach and Apel also gave each patient a stool softener and a pill for nausea but these were not controlled substances.

Board inspected its operations annually and knew that Blossom was getting its tramadol from QCP.

6. Drs. Umbach and Apel strived to make its ordering, dispensing and tracking of tramadol error-free by using a software created by MDScripts, a nationally known company that helps medical providers document and track their dispensing practices.

7. Drs. Umbach and Apel tracked every bottle of tramadol they ordered by:

(A) order date;

(B) the date their clinic received it;

(C) the shipment number; and

(D) the lot number.

8. Each patient who received a bottle of tramadol had it documented in his or her medical record, with both the patient's signature confirming receipt, and the dispensing physician's signature as well. The original signed copy with the patient's and the physician's signatures was maintained on-site at the clinic.

9. The tramadol bottles received by the clinic were stored in a closet which required a 4-digit code to enter, and inside the closet, the tramadol was stored in cabinets which had a double lock and therefore required 2 separate keys to unlock.

10. During the time that Blossom had its facility, 84 bottles of tramadol were ordered by Dr. Umbach and then transferred to Dr. Apel to give to patients in the clinic before surgery. Dr. Umbach and Dr. Apel assumed that because they worked together in the same clinic, it would not matter that the drug was ordered by one doctor but used by the other doctor since this is how medical supplies generally were treated and shared. Both Dr. Umbach and Dr. Apel were unaware of the legal limit of such transfers between doctors, and the need to register

as a "distributor" if more than 5% of the total number of dosage units of all controlled substances was exceeded.

11. On the day before surgery, each patient received a single bottle of tramadol containing 15 pills and was instructed by Dr. Umbach, Dr. Apel or the clinic staff to take one pill every 4 to 6 hours after surgery for pain in doses of 50 milligrams with a maximum of 300 milligrams per day, thus allowing the patient to treat pain for about 2 days after surgery.

12. No refills were ever given to any patient.

13. All of these intended precautions did not go according to plan. Although the MDScripts software was difficult for Blossom staff to use because it was new to them, Blossom brought in a MDScripts representatives who helped them use the software to track all the bottles of tramadol.

14. Despite its best efforts, Drs. Umbach and Apel found some discrepancies and in late 2023, they notified the DEA.

15. In December 2023, an investigator from the federal Drug Enforcement Administration visited Blossom to investigate drugs that were allegedly missing to determine if the drugs had been lost or stolen or were otherwise unaccounted for.

16. During the DEA's investigation, Blossom generated a report that showed definitively that Blossom had ordered and received a total of 750 bottles of tramadol between November 28, 2022 and October 31, 2023. Of this 750 total bottles, 706 were dispensed to patients. Dr. Apel dispensed 680 of these bottles, and Dr. Umbach dispensed 16, for a total of 696 bottles. Of this total of 696 bottles that were dispensed, 10 bottles were "voided" by Blossom. This meant that the patient was given a bottle of tramadol at the clinic the day before surgery, but the patient subsequently did not go through with the surgery, typically because their

medical condition, such as blood work or heart issues or pregnancy, made surgery too risky or they just simply changed their minds and no longer wanted the surgery. Drs. Umbach and Apel could not confirm that these 10 patients' bottles of tramadol were placed back in the inventory.

17. The bottom line of the investigation was that a total of 54 bottles of tramadol that Blossom ordered and received during the 11 months between November 28, 2022 and October 31, 2023 could not be accounted for. These 54 bottles were presumed to be stolen or lost between February 13, 2023 and November 17, 2023.

18. As soon as the Blossom staff discovered the theft/loss during the DEA investigation, Dr. Apel and Dr. Umbach directed the clinic staff to do the following:

(A) ***Police report.*** They filed a police report with the Las Vegas police department and indicated their willingness to cooperate in any investigation or provide any information the police requested.

(B) ***Interviews of both current and former staff.*** They interviewed all current staff and former staff to determine if any of them knew anything about the missing prescription bottles and what happened to them. Those employees who were currently employed were interviewed. Blossom physically interviewed all of its former staff who had been employed by Blossom and had access to the locked closet where the tramadol was stored during the one-year period in question to determine if any former staff knew anything about the suspected loss or theft.

19. ***Shutting down the in-house pharmacy facility completely.*** Despite Dr. Umbach and Dr. Apel's efforts to account for the missing 54 bottles by investigating past and current staff and numerous detailed reviews of the software records, no explanation was found, and the bottles were presumed lost or stolen. Drs. Umbach and Apel confirm that after – and as a

result of – the DEA investigation, they did not dispense any drugs at all to anyone after December 2024. In December 2024, the doctors shut down their in-house pharmacy facility completely. Since that time, neither Dr. Umbach nor Dr. Apel has dispensed any drugs at all to any patients whatsoever. Since December of 2024, Drs. Umbach and Apel have instead worked with an outside third-party independent pharmacy to dispense the drugs that they prescribe for their patients prior to surgery.

20. Dr. Apel admits that he failed to indicate on the biennial inventory if the count was taken either as of the opening of business or the close of business. He ***did*** perform the biennial inventory, he merely failed to indicate whether he performed it at the opening or closing of business.

21. Dr. Apel believed he had met these requirements of the federal and state laws including 21 U.S.C. § 842(a)(5) and 21 CFR § 1304.22(c) which requires that "records shall be maintained" of the units or volume dispensed, including "the name and address of the person to whom it was dispensed." The statute, importantly, does not say *where* the "record" of "the patient's address" should be kept, and Dr. Apel met this federal requirement by recording and keeping each patient's address in the patient's medical record. Similarly, NAC § 453.410(1)b)(1) states that the dispensing practitioner shall "ensure that each record of a controlled substance which is dispensed contains the name of the patient and, if not readily available from the practitioner's record, the patient's address." Since the patient's address *was, in fact, readily available in the patient's medical record,* the express language of this regulation does not require that it also be in the dispensing record. Hence, Dr. Apel met the legal requirements because when the tramadol was dispensed, each patient's receipt of the tramadol was recorded in the patient's medical record– *where the patient's address was clearly written and recorded* – and

both the dispensing physician and the patient personally signed for the receipt of the tramadol.

22. Dr. Apel and Dr. Umbach admit that they failed to make acquisition and distribution records of tramadol transfers from Umbach to Apel, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(a)(2)(iv) and (vii), NRS 453.245 and NRS 453.326(1)(a). The software that Blossom purchased tracked these transfers as "pod moves," but even the software's detailed records of such transfers failed to account for the missing bottles of tramadol.

23. Dr. Apel admits that he failed to record the patient's address on the tramadol dispensing records in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(c), NRS 453.246, NRS 453.326(1)a) and NAC 453.410(1)(b)(1).

24. Blossom, the clinic and medical practice, but not Dr. Umbach personally, admits that it failed to design and operate a system to disclose suspicious orders of controlled substances in violation of 21 U.S.C. § 832(a), 21 CFR § 1301.74(b), NRS 453.246 and NRS 453.326(1)(a). Dr. Umbach believed that the clinic had designed a system that would prevent theft or loss by its use of a nationally recognized software program that would make its ordering, dispensing and tracking of tramadol error-free, and by storing the tramadol in a closet which required a 4-digit code to enter, limiting the knowledge of that code only to certain staff, and inside the closet, storing the tramadol in a cabinets which had double locks and required 2 separate keys to unlock. Despite taking every reasonable measure it thought of, Blossom's efforts failed.

25. Dr. Umbach admits that he failed to register with the Drug Enforcement Administration as a distributor because he did not realize or understand that such a registration was necessary if he transferred more than 5% of the total number of dosage units of all controlled substance distribution or dispensed during a calendar year, as required by 21 U.S.C. § 822(a) and 21 CFR § 1307.11(b). Dr. Umbach thought that such transfers between doctors working in the

same clinic would be legally permissible as are all such transfers of medical equipment and medical supplies between practitioners working together in the same medical practice or the same clinic.

26. Dr. Apel admits that on or about January 17, 2024, he submitted DEA Form 106 documentation and together with a NRS 453.568 Report to the Board reporting the loss of 765 tramadol 50mg tablets resulting from Blossom's failure to provide effective controls and procedures to guard against the theft and diversion of controlled substances and to ensure all drugs were accounted for, in violation of 21 CFR § 1031.71(a), NAC 453.400 and NAC 639.742(3)(b). Dr. Apel, as stated in more detail above, thought he and Dr. Umbach and Blossom had taken every reasonable step to safeguard the tramadol supply from theft or loss, but those efforts turned out to be inadequate.

27. ***The DEA.*** Dr. Apel and Dr. Umbach were investigated by the federal Drug Enforcement Administration and the DEA's investigation was resolved when the parties completely shut down their in-house pharmacy facility and no longer dispensed any drugs at all after December 2024. No further action was taken by the DEA against either Dr. Apel or Dr. Umbach.

COUNT ONE

28. Dr. Apel and Dr. Umbach deny that they knowingly, willfully or intentionally violated, attempted to violate, assisted in violating, or conspired to violate 21 CFR § 1301.71(a), NAC 453.400 or NAC 639.742(3)(b).

COUNT TWO

29. Dr. Apel and Dr. Umbach deny that they knowingly, willfully or intentionally violated, attempted to violate, assisted in violating, or conspired to violate 21 U.S.C. § 822(a), 21

U.S.C. § 832(a), 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), 21 CFR § 1307.11(b), 21 CFR § 1304.22(a)(2)(iv) and (vii), 21 CFR § 1304.22(c), 21 CFR § 1301.74(b), NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1)(b)(1) and NAC 453.475.

COUNT THREE

30. Dr. Apel and Dr. Umbach deny that they knowingly, willfully or intentionally performed their duties as the holders of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligence manner or engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i).

COUNT FOUR

31. Dr. Apel and Dr. Umbach deny that they have knowingly, willfully or intentionally committed acts that render their registration inconsistent with the public interest and therefore should not be subject to discipline.

32. Dr. Apel and Dr. Umbach and Blossom have shut down their pharmacy and have not dispensed any drugs to any patient at all since December 2024.

DEFENSE

33. Dr. Apel and Dr. Umbach, individually and through their clinic staff, made every reasonable effort to comply with the requirements for a dispensing practitioner set out in NAC §§ 639.742 through 639.745, and did, in fact, satisfy and comply with most of the requirements.

WHEREFORE, it is requested that:

(A) the Nevada State Board of Pharmacy not discipline Dr. Apel or Dr. Umbach;

(B) Dr. Apel, Dr. Umbach and Blossom request a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present

evidence and argument on all issues involved.

Signed this 9th day of December, 2025.

/ John Snow /

John Snow
Parsons Behle & Latimer
Attorney for Drs. Apel, Dr. Umbach and Blossom Bariatrics

/ Janet I. Jenson /

Janet I. Jenson
Attorney for Drs. Apel, Dr. Umbach and Blossom Bariatrics

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

Dated this 9th day of December, 2025.

Matthew E. Apel, M.D.

CERTIFICATE OF SERVICE

I, Janet Jenson, certify that I emailed a copy of the above Answer and Notice of Defense on December 9, 2025 to:

TeamBC@Pharmacy.nv.gov and
bkandt@pharmacy.nv.gov

/ Janet I. Jenson /

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW E. APEL, MD,** **Certificate of Registration Nos.** **CS24505 and PD00589,** **and** **THOMAS UMBACH, MD,** **Certificate of Registration Nos.** **CS16064 and PD00512** **Respondents.**	**CASE NOS. 24-044-PD-A-S** **24-044-PD-B-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Matthew E. Apel MD (Apel), held Certificate of Registration Nos. CS24505 and PD00589, Respondent Thomas Umbach, MD (Umbach), held Certificate of Registration Nos. CS16064 and PD00512, all issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 28, 2023, an inspection of Apel's and Umbach's practice at Blossom Bariatric, located at 7385 S. Pecos Road – Ste 101 in Las Vegas, revealed numerous violations of law related to controlled substances.

3. Apel failed to indicate on the biennial inventory if the count was taken either as of the opening or as of the close of business, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), NRS 453.246, NRS 453.326(1)(a) and NAC 453.475.

4. Apel and Umbach failed to make and/or maintain acquisition and distribution records of tramadol, a schedule IV substance, transfers from Umbach to Apel, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(a)(2)(iv) and (vii), NRS 453.246 and NRS 453.326(1)(a).

5. Apel failed to record the address of the patient on tramadol dispensing records, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(c), NRS 453.246, NRS 453.326(1)(a) and NAC 453.410(1)(b)(1).

6. Umbach failed to design and operate a system to disclose suspicious orders of controlled substances, in violation of 21 U.S.C. § 832(a), 21 CFR § 1301.74(b), NRS 453.246 and NRS 453.326(1)(a).

7. Umbach failed to register with the Drug Enforcement Administration as a distributor after distributing more than five percent of the total number of dosage units of all controlled substances distributed and dispensed during the same calendar year, in violation of 21 U.S.C. § 822(a) and 21 CFR § 1307.11(b).

8. On or about January 17, 2024, Apel submitted DEA Form 106 documentation and together with a NRS 453.568 Report to the Board reporting the loss of 765 tramadol 50mg tablets resulting from Respondents' failure to provide effective controls and procedures to guard against the theft and diversion of controlled substances and to ensure all drugs were account for, in violation of 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b).

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APPLICABLE LAW

9. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3); NAC 639.7445.

10. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Federal and State Law - Failure to Maintain Security of Controlled Substances

14. By their actions and/or omissions as alleged in paragraph 8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT TWO

Violations of Federal and State Law - Recordkeeping

15. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a), 21 U.S.C. § 832(a), 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), 21 CFR § 1307.11(b), 21 CFR § 1304.22(a)(2)(iv) and (vii), 21 CFR § 1304.22(c), 21 CFR § 1301.74(b), NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1)(b)(1) and NAC 453.475, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

16. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have performed their duties as the holders of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(4).

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COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these Respondents.

Signed this 11th day of NOVEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THOMAS UMBACH, MD,** **Certificate of Registration Nos.** **CS16064 and PD00512,** **Respondent.**	**Case No. 24-044-PD-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 17th day of NOVEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THOMAS UMBACH, MD,** **Certificate of Registration Nos.** **CS16064 and PD00512** **Respondent.**	**Case No. 24-044-DS-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Thomas Umbach, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of November 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Thomas Umbach
c/o John Snow, Esq
201 S Main St, Suite 1800
Salt Lake City, UT 84111

Thomas Umbach
c/o John Snow, Esq.
50 W Liberty St, Suite 750
Reno, NV 89501

Thomas Umbach
c/o Janet I. Jenson, Esq.
PO Box 27727
Salt Lake City, UT 84127

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **BLOSSOM BARIATRIC,** **License No. DS00251-CS,** **MATTHEW E. APEL, MD,** **Certificate of Registration Nos.** **CS24505 and PD00589, and** **THOMAS UMBACH, MD,** **Certificate of Registration Nos.** **CS16064 and PD00512** **Respondents.**	**CASE NOS. 24-044-DS-S** **24-044-PD-A-S** **24-044-PD-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Matthew E. Apel MD (Apel), held Certificate of Registration Nos. CS24505 and PD00589, Respondent Thomas Umbach, MD (Umbach), held Certificate of Registration Nos. CS16064 and PD00512, all issued by the Board, and Respondent Blossom Bariatric, License No. DS00251-CS, was licensed by the Board.

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FACTUAL ALLEGATIONS

2. On or about December 28, 2023, an inspection of Apel's and Umbach's practice at Blossom Bariatric revealed numerous violations of law related to controlled substances.

3. Apel failed to indicate on the biennial inventory if the count was taken either as of the opening or as of the close of business, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), NRS 453.246, NRS 453.326(1)(a) and NAC 453.475.

4. Apel and Umbach failed to make and/or maintain acquisition and distribution records of tramadol, a schedule IV substance, transfers from Umbach to Apel, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(a)(2)(iv) and (vii), NRS 453.246 and NRS 453.326(1)(a).

5. Apel failed to record the address of the patient on tramadol dispensing records, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(c), NRS 453.246, NRS 453.326(1)(a) and NAC 453.410(1)(b)(1).

6. Umbach failed to design and operate a system to disclose suspicious orders of controlled substances, in violation of 21 U.S.C. § 832(a), 21 CFR § 1301.74(b), NRS 453.246 and NRS 453.326(1)(a).

7. Umbach failed to register with the Drug Enforcement Administration as a distributor after distributing more than five percent of the total number of dosage units of all controlled substances distributed and dispensed during the same calendar year, in violation of 21 U.S.C. § 822(a) and 21 CFR § 1307.11(b).

8. On or about January 17, 2024, Apel submitted DEA Form 106 documentation and together with a NRS 453.568 Report to the Board reporting the loss of 765 tramadol 50mg tablets resulting from Respondents' failure to provide effective controls and procedures to guard against the theft and diversion of controlled substances and to ensure all drugs were account for, in violation of 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b).

APPLICABLE LAW

9. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3); NAC 639.7445.

10. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Federal and State Law - Failure to Maintain Security of Controlled Substances

14. By their actions and/or omissions as alleged in paragraph 8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1301.71(a), NAC 453.400 and NAC 639.742(3)(b), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT TWO

Violations of Federal and State Law - Recordkeeping

15. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a), 21 U.S.C. § 832(a), 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), 21 CFR § 1307.11(b), 21 CFR § 1304.22(a)(2)(iv) and (vii), 21 CFR § 1304.22(c), 21 CFR § 1301.74(b), NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1)(b)(1) and NAC 453.475, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(11) and/or (12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

16. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have performed their duties as the holders of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.945(3), NAC 639.7445 and/or NRS 639.210(4).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By their actions and/or omissions as alleged in paragraphs 2-8 herein, Respondents have committed acts that render registration inconsistent with the public interest and are subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these Respondents.

Signed this 5th day of SEPTEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THOMAS UMBACH, MD,** **Certificate of Registration Nos.** **CS16064 and PD00512,** **Respondent.**	**Case No. 24-044-PD-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 5th day of SEPTEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **THOMAS UMBACH, MD,** **Certificate of Registration Nos.** **CS16064 and PD00512** **Respondent.**	**Case No. 24-044-DS-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Thomas Umbach, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Blossom Bariatric
7385 S Pecos Rd #101
Las Vegas, NV 89120

Matthew Apel
[redacted]
Las Vegas, NV [redacted]

Matthew Apel
3235 E Warm Springs Rd Suite #110
Las Vegas, NV 89120

Thomas Umbach
[redacted]
Henderson, NV [redacted]

Thomas Umbach
3235 E Warm Springs Rd Suite #100
Las Vegas, NV 89120

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **vs.** **MATTHEW E. APEL, M.D., Certificate of Registration Nos. CS24505 and PD00589, and** **THOMAS UMBACH, M.D., Certificate of Registration Nos. CS16064 and PD00512,** **Respondents.**	**Case No. 24-044-PD-A-S** **24-044-PD-B-S** **ANSWER AND NOTICE OF DEFENSE TO FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

Respondents, above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declare:

1. Dr. Umbach and Dr. Apel are bariatric surgeons who perform hundreds of surgeries every year on morbidly obese patients. Their clinic is Blossom Bariatrics in Las Vegas. Dr. Apel and Dr. Umbach are licensed as "dispensing practitioners" pursuant to the Nevada Administrative Code §§ 639.742 through 639.745.

2. A large majority of the patients of Blossom Bariatrics are from out-of-state. They typically fly in to Las Vegas from all over the country and stay in hotels for the few days that their surgeries require. On the first day, the patients go to Blossom to have preparatory medical work done. This includes testing their blood pressure, having blood work, taking cardiology exams to determine if their hearts are healthy enough for surgery, and getting an endoscopy.

They talk with the staff and the doctors about what to expect, and if they pass all their tests, they are scheduled for surgery the next day at an ambulatory surgical center.

3. In an effort to provide the best care for their patients, Dr. Umbach opened a small facility at Blossom and registered himself and Dr. Apel as "dispensing practitioners." They used the facility for one purpose only which was to provide one drug – tramadol – to their patients for use after their surgery the next day.[1] Each patient received a single bottle of tramadol containing 15 pills and each patient was instructed by the doctor or staff to take one pill every 4 to 6 hours after surgery for pain in doses of 50 milligrams with a maximum of 300 milligrams per day, thus allowing the patient to treat pain for about 2 days after surgery. No patient was ever given more than one bottle, or more than 15 pills.

4. Dr. Umbach wanted to provide the tramadol directly to the patients because it was difficult for most of them to find a pharmacy, given that they were typically from out-of-town and did not know where a pharmacy was, and they had no relationship with any local pharmacy. Also, the patients needed the tramadol for their surgery the next morning, and not every pharmacy had tramadol on hand when patients showed up with their prescription. Dr. Umbach believed that, by making tramadol available at the clinic, he was providing them the best and most convenient care and helping them prepare for their surgery.

5. Therefore, Drs. Apel and Umbach registered as "dispensing practitioners" and used their onsite drug facility for Blossom's patients only. Blossom ordered its one drug – tramadol – from Quality Care Partners ("QCP"), a legitimate pharmaceutical supplier. Blossom operated its practitioner-dispensing inhouse facility for five years, and the Nevada Pharmacy

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[1] Drs. Umbach and Apel also gave each patient a stool softener and a pill for nausea but these were not controlled substances.

Board inspected its operations annually and knew that Blossom was getting its tramadol from QCP.

6. Drs. Umbach and Apel strived to make its ordering, dispensing and tracking of tramadol error-free by using a software created by MDScripts, a nationally known company that helps medical providers document and track their dispensing practices.

7. Drs. Umbach and Apel tracked every bottle of tramadol they ordered by:

(A) order date;

(B) the date their clinic received it;

(C) the shipment number; and

(D) the lot number.

8. Each patient who received a bottle of tramadol had it documented in his or her medical record, with both the patient's signature confirming receipt, and the dispensing physician's signature as well. The original signed copy with the patient's and the physician's signatures was maintained on-site at the clinic.

9. The tramadol bottles received by the clinic were stored in a closet which required a 4-digit code to enter, and inside the closet, the tramadol was stored in cabinets which had a double lock and therefore required 2 separate keys to unlock.

10. During the time that Blossom had its facility, 84 bottles of tramadol were ordered by Dr. Umbach and then transferred to Dr. Apel to give to patients in the clinic before surgery. Dr. Umbach and Dr. Apel assumed that because they worked together in the same clinic, it would not matter that the drug was ordered by one doctor but used by the other doctor since this is how medical supplies generally were treated and shared. Both Dr. Umbach and Dr. Apel were unaware of the legal limit of such transfers between doctors, and the need to register

as a "distributor" if more than 5% of the total number of dosage units of all controlled substances was exceeded.

11. On the day before surgery, each patient received a single bottle of tramadol containing 15 pills and was instructed by Dr. Umbach, Dr. Apel or the clinic staff to take one pill every 4 to 6 hours after surgery for pain in doses of 50 milligrams with a maximum of 300 milligrams per day, thus allowing the patient to treat pain for about 2 days after surgery.

12. No refills were ever given to any patient.

13. All of these intended precautions did not go according to plan. Although the MDScripts software was difficult for Blossom staff to use because it was new to them, Blossom brought in a MDScripts representatives who helped them use the software to track all the bottles of tramadol.

14. Despite its best efforts, Drs. Umbach and Apel found some discrepancies and in late 2023, they notified the DEA.

15. In December 2023, an investigator from the federal Drug Enforcement Administration visited Blossom to investigate drugs that were allegedly missing to determine if the drugs had been lost or stolen or were otherwise unaccounted for.

16. During the DEA's investigation, Blossom generated a report that showed definitively that Blossom had ordered and received a total of 750 bottles of tramadol between November 28, 2022 and October 31, 2023. Of this 750 total bottles, 706 were dispensed to patients. Dr. Apel dispensed 680 of these bottles, and Dr. Umbach dispensed 16, for a total of 696 bottles. Of this total of 696 bottles that were dispensed, 10 bottles were "voided" by Blossom. This meant that the patient was given a bottle of tramadol at the clinic the day before surgery, but the patient subsequently did not go through with the surgery, typically because their

medical condition, such as blood work or heart issues or pregnancy, made surgery too risky or they just simply changed their minds and no longer wanted the surgery. Drs. Umbach and Apel could not confirm that these 10 patients' bottles of tramadol were placed back in the inventory.

17. The bottom line of the investigation was that a total of 54 bottles of tramadol that Blossom ordered and received during the 11 months between November 28, 2022 and October 31, 2023 could not be accounted for. These 54 bottles were presumed to be stolen or lost between February 13, 2023 and November 17, 2023.

18. As soon as the Blossom staff discovered the theft/loss during the DEA investigation, Dr. Apel and Dr. Umbach directed the clinic staff to do the following:

(A) ***Police report.*** They filed a police report with the Las Vegas police department and indicated their willingness to cooperate in any investigation or provide any information the police requested.

(B) ***Interviews of both current and former staff.*** They interviewed all current staff and former staff to determine if any of them knew anything about the missing prescription bottles and what happened to them. Those employees who were currently employed were interviewed. Blossom physically interviewed all of its former staff who had been employed by Blossom and had access to the locked closet where the tramadol was stored during the one-year period in question to determine if any former staff knew anything about the suspected loss or theft.

19. ***Shutting down the in-house pharmacy facility completely.*** Despite Dr. Umbach and Dr. Apel's efforts to account for the missing 54 bottles by investigating past and current staff and numerous detailed reviews of the software records, no explanation was found, and the bottles were presumed lost or stolen. Drs. Umbach and Apel confirm that after – and as a

result of – the DEA investigation, they did not dispense any drugs at all to anyone after December 2024. In December 2024, the doctors shut down their in-house pharmacy facility completely. Since that time, neither Dr. Umbach nor Dr. Apel has dispensed any drugs at all to any patients whatsoever. Since December of 2024, Drs. Umbach and Apel have instead worked with an outside third-party independent pharmacy to dispense the drugs that they prescribe for their patients prior to surgery.

20. Dr. Apel admits that he failed to indicate on the biennial inventory if the count was taken either as of the opening of business or the close of business. He ***did*** perform the biennial inventory, he merely failed to indicate whether he performed it at the opening or closing of business.

21. Dr. Apel believed he had met these requirements of the federal and state laws including 21 U.S.C. § 842(a)(5) and 21 CFR § 1304.22(c) which requires that "records shall be maintained" of the units or volume dispensed, including "the name and address of the person to whom it was dispensed." The statute, importantly, does not say *where* the "record" of "the patient's address" should be kept, and Dr. Apel met this federal requirement by recording and keeping each patient's address in the patient's medical record. Similarly, NAC § 453.410(1)b)(1) states that the dispensing practitioner shall "ensure that each record of a controlled substance which is dispensed contains the name of the patient and, if not readily available from the practitioner's record, the patient's address." Since the patient's address *was, in fact, readily available in the patient's medical record,* the express language of this regulation does not require that it also be in the dispensing record. Hence, Dr. Apel met the legal requirements because when the tramadol was dispensed, each patient's receipt of the tramadol was recorded in the patient's medical record– *where the patient's address was clearly written and recorded* – and

both the dispensing physician and the patient personally signed for the receipt of the tramadol.

22. Dr. Apel and Dr. Umbach admit that they failed to make acquisition and distribution records of tramadol transfers from Umbach to Apel, in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(a)(2)(iv) and (vii), NRS 453.245 and NRS 453.326(1)(a). The software that Blossom purchased tracked these transfers as "pod moves," but even the software's detailed records of such transfers failed to account for the missing bottles of tramadol.

23. Dr. Apel admits that he failed to record the patient's address on the tramadol dispensing records in violation of 21 U.S.C. § 842(a)(5), 21 CFR § 1304.22(c), NRS 453.246, NRS 453.326(1)a) and NAC 453.410(1)(b)(1).

24. Blossom, the clinic and medical practice, but not Dr. Umbach personally, admits that it failed to design and operate a system to disclose suspicious orders of controlled substances in violation of 21 U.S.C. § 832(a), 21 CFR § 1301.74(b), NRS 453.246 and NRS 453.326(1)(a). Dr. Umbach believed that the clinic had designed a system that would prevent theft or loss by its use of a nationally recognized software program that would make its ordering, dispensing and tracking of tramadol error-free, and by storing the tramadol in a closet which required a 4-digit code to enter, limiting the knowledge of that code only to certain staff, and inside the closet, storing the tramadol in a cabinets which had double locks and required 2 separate keys to unlock. Despite taking every reasonable measure it thought of, Blossom's efforts failed.

25. Dr. Umbach admits that he failed to register with the Drug Enforcement Administration as a distributor because he did not realize or understand that such a registration was necessary if he transferred more than 5% of the total number of dosage units of all controlled substance distribution or dispensed during a calendar year, as required by 21 U.S.C. § 822(a) and 21 CFR § 1307.11(b). Dr. Umbach thought that such transfers between doctors working in the

same clinic would be legally permissible as are all such transfers of medical equipment and medical supplies between practitioners working together in the same medical practice or the same clinic.

26. Dr. Apel admits that on or about January 17, 2024, he submitted DEA Form 106 documentation and together with a NRS 453.568 Report to the Board reporting the loss of 765 tramadol 50mg tablets resulting from Blossom's failure to provide effective controls and procedures to guard against the theft and diversion of controlled substances and to ensure all drugs were accounted for, in violation of 21 CFR § 1031.71(a), NAC 453.400 and NAC 639.742(3)(b). Dr. Apel, as stated in more detail above, thought he and Dr. Umbach and Blossom had taken every reasonable step to safeguard the tramadol supply from theft or loss, but those efforts turned out to be inadequate.

27. ***The DEA.*** Dr. Apel and Dr. Umbach were investigated by the federal Drug Enforcement Administration and the DEA's investigation was resolved when the parties completely shut down their in-house pharmacy facility and no longer dispensed any drugs at all after December 2024. No further action was taken by the DEA against either Dr. Apel or Dr. Umbach.

COUNT ONE

28. Dr. Apel and Dr. Umbach deny that they knowingly, willfully or intentionally violated, attempted to violate, assisted in violating, or conspired to violate 21 CFR § 1301.71(a), NAC 453.400 or NAC 639.742(3)(b).

COUNT TWO

29. Dr. Apel and Dr. Umbach deny that they knowingly, willfully or intentionally violated, attempted to violate, assisted in violating, or conspired to violate 21 U.S.C. § 822(a), 21

U.S.C. § 832(a), 21 U.S.C. § 842(a)(5), 21 CFR § 1304.11(a), 21 CFR § 1307.11(b), 21 CFR § 1304.22(a)(2)(iv) and (vii), 21 CFR § 1304.22(c), 21 CFR § 1301.74(b), NRS 453.246, NRS 453.326(1)(a), NAC 453.410(1)(b)(1) and NAC 453.475.

COUNT THREE

30. Dr. Apel and Dr. Umbach deny that they knowingly, willfully or intentionally performed their duties as the holders of controlled substance and dispensing practitioner registrations in an incompetent, unskillful or negligence manner or engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i).

COUNT FOUR

31. Dr. Apel and Dr. Umbach deny that they have knowingly, willfully or intentionally committed acts that render their registration inconsistent with the public interest and therefore should not be subject to discipline.

32. Dr. Apel and Dr. Umbach and Blossom have shut down their pharmacy and have not dispensed any drugs to any patient at all since December 2024.

DEFENSE

33. Dr. Apel and Dr. Umbach, individually and through their clinic staff, made every reasonable effort to comply with the requirements for a dispensing practitioner set out in NAC §§ 639.742 through 639.745, and did, in fact, satisfy and comply with most of the requirements.

WHEREFORE, it is requested that:

(A) the Nevada State Board of Pharmacy not discipline Dr. Apel or Dr. Umbach;

(B) Dr. Apel, Dr. Umbach and Blossom request a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present

evidence and argument on all issues involved.

Signed this 9th day of December, 2025.

/ John Snow /

John Snow
Parsons Behle & Latimer
Attorney for Drs. Apel, Dr. Umbach and Blossom Bariatrics

/ Janet I. Jenson /

Janet I. Jenson
Attorney for Drs. Apel, Dr. Umbach and Blossom Bariatrics

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

Dated this 9th day of December, 2025.

Thomas Umbach, M.D.

CERTIFICATE OF SERVICE

I, Janet Jenson, certify that I emailed a copy of the above Answer and Notice of Defense on December 9, 2025 to:

TeamBC@Pharmacy.nv.gov and
bkandt@pharmacy.nv.gov

/ Janet I. Jenson /

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN, Certificate of Registration Nos. CS34530 and PR16791,** **Respondent.**	**CASE NO. 24-213-CS-S** **SECOND AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Susan Lee Nytes, APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS34530, and a Nevada prescribing registration, Certificate of Registration No. PR16791, both issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 13, 2012, the Iowa Board of Nursing (IBN) and Respondent entered a settlement agreement in Case No. 10-147, imposing discipline on Respondent's IBN License No. 119268 to practice nursing for cause relating to controlled substances.

3. Respondent failed to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration and was subsequently issued Certificate of Registration No. CS34530.

4. Respondent issued at least one hundred forty-eight (148) controlled substance prescriptions for ninety (90) unique patients in Nevada between April 18, 2024, and June 11, 2024, without a valid registration from the U.S. Drug Enforcement Administration (DEA) for Nevada and without a valid practice location on file with the Board.

5. On or about June 13, 2024, Board staff served Respondent with an order to immediately cease and desist prescribing controlled substances for Nevada patients without a valid DEA registration for Nevada.

6. On or about January 16, 2025, the Nevada State Board of Nursing (NSBN) and Respondent entered a settlement agreement and order in Case Nos. 2023100062, 2024040122 and 2024060231, imposing discipline on Respondent's NSBN License No. 835435 to practice nursing for engaging in conduct in violation of the standards of practice established by the NSBN, specifically for violation of NRS 632.347(1)(g) and NAC 632.890(26) related to unsafely prescribing controlled substances.

7. Respondent failed to timely report to the Board the disciplinary action in NSBN Case Nos. 2023100062, 2024040122 and 2024060231.

8. On or about September 16, 2025, Respondent unlawfully accessed the Prescription Monitoring Program (PMP) database, reviewed and subsequently disseminated the patient utilization report for J.S., with whom Respondent had not established a bona fide therapeutic relationship.

9. On or about September 17, 2025, Respondent's access to the PMP database was suspended pursuant to NAC 453.078.

APPLICABLE LAW

10. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance in Nevada. 21 U.S.C. § 822(a)(2) and (e)(1); 21

U.S.C. § 823(f); 21 C.F.R. § 1301.12; 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.1375; NRS 639.235(1).

11. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

12. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements of NRS 639.2391-.23914, *inclusive*. 21 CFR § 1306.04(a); NRS 453.381(1).

13. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

14. Registration must be for a valid practice location. 21 U.S.C. § 822(e)(1); 21 C.F.R. § 1301.12; NAC 453.130; NAC 639.846.

15. The holder of a controlled substance registration shall report any administrative action taken against the holder by any professional licensing board not later than 30 days after the final disposition of the administrative action. NAC 639.229(1)(b).

16. Patient utilization reports and all data in the PMP database constitute Protected Health Information (PHI); unauthorized access constitutes a criminal offense. 42 U.S.C. §1320d-6; 45 C.F.R. Part 160 and Part 164, Subparts A and E; NRS 453.164(8); NRS 453.552(2).

17. The Executive Secretary on behalf of the Board may suspend or terminate, before a hearing, the Internet access of a practitioner to the PMP database if the practitioner accesses the database for an unauthorized purpose. NAC 453.078; NAC 453.084.

18. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

19. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

20. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9); NAC 639.900(8).

21. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(a); NRS 639.210(10); NAC 639.900(9).

22. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11); NAC 639.900(10).

23. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

24. The Board may suspend or revoke a controlled substance registration upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Furnishing False Material Information to Board

25. By failing to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration as alleged in paragraph 3 herein, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9), NRS 639.210(12) and/or NAC 639.900(8).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

26. By failing to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration as alleged in paragraph 3 herein, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(10) and/or NAC 639.900(9).

COUNT THREE
Violations of Federal Controlled Substances Act – Unlawfully Issuing Prescriptions

27. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location as alleged in paragraph 4 herein, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2) and (e)(1), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 C.F.R. § 1301.12 and/or 21 CFR § 1306.03(a)(1). By unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1306.04(a). Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(11) and/or NAC 639.900(10).

COUNT FOUR

Violations of State Controlled Substances Act – Unlawfully Issuing Prescriptions

28. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location as alleged in paragraph 4 herein, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.1375, NRS 639.235(1), NRS 639.2813(1), NAC 453.130 and/or NAC 639.846. By unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1) and/or NRS 639.2391-.23914, *inclusive*. Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12), NRS 639.23916(3)(b) and/or NAC 639.900(14).

COUNT FIVE

Violation of State Law – Failure to Report

29. By failing to timely report to the Board the disciplinary action in NSBN Case Nos. 2023100062, 2024040122 and 2024060231, as alleged in paragraph 7 herein, Respondent violated NAC 639.229(1)(b) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(12) and/or NAC 639.900(14).

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COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

30. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location on file with the Board, by unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, and by failing to timely report to the Board the NSBN's disciplinary action, Respondent has performed her duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1), NRS 639.210(4) and NAC 639.900(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing without DEA Registration for Nevada

31. By issuing controlled substance prescriptions without a valid DEA registration for Nevada, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(4) and/or NAC 639.900(4).

COUNT EIGHT

Violations of Law - Prescription Monitoring Program

32. By unlawfully accessed the Prescription Monitoring Program (PMP) database and reviewed the patient utilization report for J.S., with whom Respondent had not established a bona fide therapeutic relationship, as alleged in paragraph 8 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. §1320d-6, 45 C.F.R. Part 160 and Part 164, Subparts A and E, NRS 453.164(8) and/or NRS 453.552(2), and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

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COUNT NINE

Commission of Acts that Render Registration Inconsistent with the Public Interest

33. By her actions and omissions as alleged herein, Respondent has committed acts that render her registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(12) and/or NAC 639.900.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of this respondent.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**Case No. 24-213-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Second Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**Case No. 24-213-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Second Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Second Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Second Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

SUSAN LEE NYTES, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of January 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Susan Nytes, APRN
[redacted]
Las Vegas, NV [redacted]

Advanced Pain Management & Addiction
c/o Susan Nytes, APRN
6135 Harrison Dr, #3A
Las Vegas, NV 89120

Susan Nytes, APRN
[redacted]
7435 S Eastern Ave Ste 105
Las Vegas, NV 89123

And Via Electronic Mail to: Susan Nytes [redacted]@aol.com

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
SEP 22 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**CASE NO. 24-213-CS-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Susan Lee Nytes, APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS34530, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 13, 2012, the Iowa Board of Nursing (IBN) and Respondent entered a settlement agreement in Case No. 10-147, imposing discipline on Respondent's IBN License No. 119268 to practice nursing for cause relating to controlled substances.

3. Respondent failed to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration, and was subsequently issued Certificate of Registration No. CS34530.

4. Respondent issued at least one hundred forty-eight (68) controlled substance prescriptions for ninety (90) unique patients in Nevada between April 18, 2024, and June 11, 2024, without a valid registration from the U.S. Drug Enforcement Administration (DEA) for Nevada and without a valid practice location on file with the Board.

5. On or about June 13, 2024, Board staff served Respondent with an order to immediately cease and desist prescribing controlled substances for Nevada patients without a valid DEA registration for Nevada.

6. On or about January 16, 2025, the Nevada State Board of Nursing (NSBN) and Respondent entered a settlement agreement and order in Case Nos. 2023100062, 2024040122 and 2024060231, imposing discipline on Respondent's NSBN License No. 835435 to practice nursing for engaging in conduct in violation of the standards of practice established by the NSBN, specifically for violation of NRS 632,347(1)(g) and NAC 632.890(26) related to unsafely prescribing controlled substances.

7. Respondent failed to timely report to the Board the disciplinary action in NSBN Case Nos. 2023100062, 2024040122 and 2024060231.

8. On or about September 16, 2025, Respondent unlawfully accessed the Prescription Monitoring Program (PMP) database, and reviewed and subsequently disseminated the patient utilization report for J.S., with whom Respondent had not established a bona fide therapeutic relationship.

9. On or about September 17, 2025, Respondent's access to the PMP database was suspended pursuant to NAC 453.078.

APPLICABLE LAW

10. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance in Nevada. 21 U.S.C. § 822(a)(2) and (e)(1); 21

U.S.C. § 823(f); 21 C.F.R. § 1301.12; 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.1375; NRS 639.235(1).

11. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

12. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements of NRS 639.2391-.23914, *inclusive*. 21 CFR § 1306.04(a); NRS 453.381(1).

13. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

14. Registration must be for a valid practice location. 21 U.S.C. § 822(e)(1); 21 C.F.R. § 1301.12; NAC 453.130; NAC 639.846.

15. The holder of a controlled substance registration shall report any administrative action taken against the holder by any professional licensing board not later than 30 days after the final disposition of the administrative action. NAC 639.229(1)(b).

16. Patient utilization reports and all data in the PMP database constitute Protected Health Information (PHI); unauthorized access constitutes a criminal offense. 42 U.S.C. §1320d-6; 45 C.F.R. Part 160 and Part 164, Subparts A and E; NRS 453.164(8); NRS 453.552(2).

17. The Executive Secretary on behalf of the Board may suspend or terminate, before a hearing, the Internet access of a practitioner to the PMP database if the practitioner accesses the database for an unauthorized purpose. NAC 453.078; NAC 453.084.

18. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

19. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

20. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9); NAC 639.900(8).

21. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(a); NRS 639.210(10); NAC 639.900(9).

22. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11); NAC 639.900(10).

23. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

24. The Board may suspend or revoke a controlled substance registration upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Furnishing False Material Information to Board

25. By failing to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration as alleged in paragraph 3 herein, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9), NRS 639.210(12) and/or NAC 639.900(8).

COUNT TWO

Obtaining Registration by False or Fraudulent Application

26. By failing to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration as alleged in paragraph 3 herein, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(10) and/or NAC 639.900(9).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Prescriptions

27. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location as alleged in paragraph 4 herein, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2) and (e)(1), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 C.F.R. § 1301.12 and/or 21 CFR § 1306.03(a)(1). By unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1306.04(a). Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(11) and/or NAC 639.900(10).

COUNT FOUR

Violations of State Controlled Substances Act – Unlawfully Issuing Prescriptions

28. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location as alleged in paragraph 4 herein, Respondent

falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.1375, NRS 639.235(1), NRS 639.2813(1), NAC 453.130 and/or NAC 639.846. By unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1) and/or NRS 639.2391-.23914, *inclusive*. Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12), NRS 639.23916(3)(b) and/or NAC 639.900(14).

COUNT FIVE

Violation of State Law – Failure to Report

29. By failing to timely report to the Board the disciplinary action in NSBN Case Nos. 2023100062, 2024040122 and 2024060231, as alleged in paragraph 7 herein, Respondent violated NAC 639.229(1)(b) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(12) and/or NAC 639.900(14).

COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

30. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location on file with the Board, by unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, and by failing to timely report to the Board the NSBN's disciplinary action, Respondent has performed her duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1), NRS 639.210(4) and NAC 639.900(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing without DEA Registration for Nevada

31. By issuing controlled substance prescriptions without a valid DEA registration for Nevada, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(4) and/or NAC 639.900(4).

COUNT EIGHT

Violations of Law - Prescription Monitoring Program

32. By unlawfully accessed the Prescription Monitoring Program (PMP) database and reviewed the patient utilization report for J.S., with whom Respondent had not established a bona fide therapeutic relationship, as alleged in paragraph 8 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. §1320d-6, 45 C.F.R. Part 160 and Part 164, Subparts A and E, NRS 453.164(8) and/or NRS 453.552(2), and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT NINE

Commission of Acts that Render Registration Inconsistent with the Public Interest

33. By her actions and omissions as alleged herein, Respondent has committed acts that render her registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 22nd day of September 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**Case No. 24-213-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22ND day of SEPTEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**Case No. 24-213-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

SUSAN LEE NYTES, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of September 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Susan Nytes, APRN
[redacted]
Las Vegas, NV [redacted]

Advanced Pain Management & Addiction
c/o Susan Nytes, APRN
6135 Harrison Drive #3A
Las Vegas, NV 89120

Advanced Pain Management & Addiction
c/o Susan Nytes, APRN
2850 W Horizon Ridge Pkwy. Ste. 200-218
Las Vegas, NV 89052

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**CASE NO. 24-213-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Susan Lee Nytes, APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS34530, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about September 13, 2012, the Iowa Board of Nursing (IBN) and Respondent entered a settlement agreement in Case No. 10-147, imposing discipline on Respondent's IBN License No. 119268 to practice nursing for cause relating to controlled substances.

3. Respondent failed to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration, and was subsequently issued Certificate of Registration No. CS34530.

4. Respondent issued at least one hundred forty-eight (68) controlled substance prescriptions for ninety (90) unique patients in Nevada between April 18, 2024, and June 11,

2024, without a valid registration from the U.S. Drug Enforcement Administration (DEA) for Nevada and without a valid practice location on file with the Board.

5. On or about June 13, 2024, Board staff served Respondent with an order to immediately cease and desist prescribing controlled substances for Nevada patients without a valid DEA registration for Nevada.

6. On or about January 16, 2025, the Nevada State Board of Nursing (NSBN) and Respondent entered a settlement agreement and order in Case Nos. 2023100062, 2024040122 and 2024060231, imposing discipline on Respondent's NSBN License No. 835435 to practice nursing for engaging in conduct in violation of the standards of practice established by the NSBN, specifically for violation of NRS 632,347(1)(g) and NAC 632.890(26) related to unsafely prescribing controlled substances.

7. Respondent failed to timely report to the Board the disciplinary action in NSBN Case Nos. 2023100062, 2024040122 and 2024060231.

APPLICABLE LAW

8. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance in Nevada. 21 U.S.C. § 822(a)(2) and (e)(1); 21 U.S.C. § 823(f); 21 C.F.R. § 1301.12; 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

9. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

10. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements of NRS 639.2391-.23914, *inclusive*. 21 CFR § 1306.04(a); NRS 453.381(1).

11. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

12. Registration must be for a valid practice location. 21 U.S.C. § 822(e)(1); 21 C.F.R. § 1301.12; NAC 453.130; NAC 639.846.

13. The holder of a controlled substance registration shall report any administrative action taken against the holder by any professional licensing board not later than 30 days after the final disposition of the administrative action. NAC 639.229(1)(b).

14. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

16. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

17. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

18. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

19. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

20. The Board may suspend or revoke a controlled substance registration upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Furnishing False Material Information to Board

21. By failing to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

22. By failing to disclose to the Board the disciplinary order in IBN Case No. 10-147 on her 2022 application for a controlled substance registration, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

COUNT THREE
Violations of Federal Controlled Substances Act – Unlawfully Issuing Prescriptions

23. By issuing controlled substance prescriptions without a valid DEA registration for Nevada, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2) and (e)(1), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 C.F.R. § 1301.12 and/or 21 CFR § 1306.03(a)(1). By unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, violated, attempted to violate, assisted or abetted in the violation of or conspired to

violate 21 CFR § 1306.04(a). Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT FOUR

Violations of State Controlled Substances Act – Unlawfully Issuing Prescriptions

24. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location on file with the Board, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1), NRS 639.2813(1), NAC 453.130 and/or NAC 639.846. By unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1) and/or NRS 639.2391-.23914, *inclusive*. Respondent is therefore subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT FIVE

Violation of State Law – Failure to Report

25. By failing to timely report to the Board the disciplinary action in NSBN Case Nos. 2023100062, 2024040122 and 2024060231, Respondent violated NAC 639.229(1)(b) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT SIX

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

26. By issuing controlled substance prescriptions without a valid DEA registration for Nevada and without a valid practice location on file with the Board, by unsafely prescribing controlled substances as detailed in the NSBN's order in Case Nos. 2023100062, 2024040122 and 2024060231, and by failing to timely report to the Board the NSBN's disciplinary action, Respondent has performed her duties as the holder of a Nevada controlled substance registration

in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing without DEA Registration for Nevada

27. By issuing controlled substance prescriptions without a valid DEA registration for Nevada, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT

Commission of Acts that Render Registration Inconsistent with the Public Interest

28. By her actions and omissions as alleged herein, Respondent has committed acts that render her registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 5th day of September 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**Case No. 24-213-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 5th day of September 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUSAN LEE NYTES, APRN,** **Certificate of Registration No. CS34530,** **Respondent.**	**Case No. 24-213-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

SUSAN LEE NYTES, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of Sept. 2025, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Susan Nytes, APRN
[redacted]
Las Vegas, NV [redacted]

Susan Nytes, APRN c/o
Advanced Pain Management and Addiction
6135 Harrison Dr.
Las Vegas, NV 89120

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5D

FILED
JAN 7 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **IVAN LEE GOLDSMITH, MD,** **Certificate of Registration No. CS33713,** **Respondent.**	**Case No. 24-488-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because at the time of the events alleged herein, Respondent Ivan Lee Goldsmith, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS33713, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent has a record of prior discipline from the Board in case no. 17-055-PD-related to sterile compounding and in case no. 17-101-CS-S for accessing the Prescription Monitoring Program (PMP) database unlawfully.

3. From December 11, 2023 to December 11, 2024, Respondent failed to review patient utilization reports in the PMP database prior to issuing controlled substance prescriptions for twenty-five (25) unique patients.

4. Respondent failed to timely renew his Certificate of Registration No. CS33713, which expired on October 31, 2024.

5. Respondent issued the following prescriptions for controlled substances between November 1, 2024 and December 14, 2024:

Patient S.C. – Prescription No. 4547095 issued 11/7/24 dispensed by Smith's Pharmacy

Patient S.B. – Prescription No. 923416 issued 11/8/24 dispensed by Family Care Pharmacy

Patient S.A. – Prescription No. 2092432 issued 11/11/24 dispensed by Costco Pharmacy

Patient E.B. – Prescription No. 923771 issued 11/13/24 dispensed by Family Care Pharmacy

Patient J.K. – Prescription No. 4474279 issued 11/14/24 dispensed by Albertson's Pharmacy

Patient C.B. – Prescription No. 2709784 issued 11/20/24 dispensed by Nevada CVS Pharmacy

Patient K.G. – Prescription No. 2037233 issued 11/20/24 dispensed by Warm Springs Rd CVS

Patient J.S. – Prescription No. 4576983 issued 11/22/24 dispensed by Smith's Pharmacy

Patient L.B. – Prescription No. 925137 issued 12/4/24 dispensed by Family Care Pharmacy

Patient G.L. – Prescription No. 1201973 issued 12/4/24 dispensed by Warm Springs Rd CVS

Patient T.S. – Prescription No. 2034647 issued 12/11/24 dispensed by Smith's Pharmacy #367

Patient S.B. – Prescription No. 925579 issued 12/11/24 dispensed by Family Care Pharmacy

6. Respondent renewed his Certificate of Registration No. CS33713 on December 14, 2024.

APPLICABLE LAW

7. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance in Nevada. 21 U.S.C. § 822(a)(2) and (e)(1); 21 U.S.C. § 823(f); 21 C.F.R. § 1301.12; 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

8. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

9. A prescribing practitioner shall only issue a controlled substance prescription after review of a patient's utilization report in the PMP database in conformance with NRS 639.23507.

10. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

12. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

13. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

14. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to submit the application for renewal. NRS 639.210(13).

15. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Failure to Time Renew Controlled Substance Registration

16. By failing to timely renew his Certificate of Registration CS33713 prior to issuing controlled substance prescriptions as alleged in paragraphs 4-6 herein, Respondent is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(13) and/or NRS 639.255.

COUNT TWO

Violations of Federal Controlled Substances Act

17. By issuing controlled substance prescriptions without a valid registration as alleged in paragraphs 4-6 herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2) and (e)(1), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 C.F.R. § 1301.12 and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT THREE

Violations of State Controlled Substances Act

18. By issuing controlled substance prescriptions without a valid registration as alleged in paragraphs 4-6 herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

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COUNT FOUR

Violation of State Law – Failure to Review PMP when Prescribing a Controlled Substance

19. By failing to review patient utilization reports in the PMP database prior to issuing controlled substance prescriptions as detailed in Paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT FIVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

20. By his acts and omissions as alleged herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(4) and/or NRS 639.23916(3)(b).

COUNT SIX

Unprofessional Conduct – Unlicensed Practice

21. By issuing controlled substance prescriptions without a valid registration as alleged in paragraphs 4-6 herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SEVEN

Commission of Acts that Render Registration Inconsistent with the Public Interest

22. By issuing controlled substance prescriptions without a valid registration as alleged in paragraphs 4-6 herein, and falsely representing himself as a practitioner entitled to write prescriptions in this state, Respondent committed acts that render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **IVAN LEE GOLDSMITH, MD,** **Certificate of Registration No. CS33713,** **Respondent.**	**Case No. 24-488-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **IVAN LEE GOLDSMITH, MD,** **Certificate of Registration No. CS33713,** **Respondent.**	**Case No. 24-488-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

Ivan Lee Goldsmith, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of January 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Ivan Lee Goldsmith, MD
[redacted]
Las Vegas, NV [redacted]

Ivan Lee Goldsmith, MD
[redacted]
Henderson, NV [redacted]

Ivan Lee Goldsmith, MD
[redacted]
Henderson NV [redacted]

Innovative Care Physicians
c/o Ivan Lee Goldsmith, MD
2350 S Jones Blvd
Las Vegas, NV 89146

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
JAN 27 2026
NEVADA STATE BOARD
OF PHARMACY

CLARK HILL PLC
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Nevada Bar No. 14103
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1700 South Pavilion Center Drive, Suite 500
Las Vegas, Nevada 89135
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Fax: (702) 778-9709

Attorneys for Respondent Ivan Lee Goldsmith, M.D.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. IVAN LEE GOLDSMITH, M.D., Certificate of Registration No. CS33713, Respondent.	CASE NO.: 24-488-CS-S **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-titled matter before the Nevada States Board of Pharmacy (the "Board"), declares:

1. That his objections to the Notice of Intended Action and Accusation (the "Notice") as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

a. This action is barred by the doctrine of laches. The Notice addresses conduct alleged to have occurred in 2023 and 2024. The Board filed its Complaint on January 7, 2026, years after the alleged conduct - without a valid excuse for such delay, as a result of which Dr. Goldsmith was prejudiced. Implicit in the Board's statutes (NRS 639.241, *et. seq.*) and its regulations (NAC 639.120, *et. seq.*) is an obligation to proceed promptly and fairly against Respondent. Because the Board did not promptly determine whether the Notice would be filed against Dr. Goldsmith, it would be inequitable and unjust to proceed.

b. Respondent denies that he ever knowingly or intentionally violated any state law or regulation, including, but not limited to 21 U.S.C. § 822(a)(2) and (e)(1), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 C.F.R. § 1301.12, 21 C.F.R. § 1306.03(a)(1), NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1), NRS 639.2813(1), NRS 639.23507, NAC 639.945(1)(i) and (k),or any other provision of NRS 454 or NRS 639 alleged to have been violated.

2. That, in answer to the Notice, he admits, denies, and alleges as follows:

a. Respondent admits that the Board has jurisdiction over this matter.

b. Respondent admits the allegations in Paragraph 2 of the Notice.

c. Respondent denies the allegation in Paragraph 3 of the Notice.

d. Respondent admits the allegations in Paragraph 4 of the Notice.

e. Respondent denies the allegations in Paragraph 5.

f. Respondent admits the allegations in Paragraph 6.

g. The allegations in Paragraphs 7 through 15 contain conclusions of law for which no response is required.

h. For the reasons set forth in his objections, and based on his admissions and denials of the allegations in the preceding paragraphs, Respondent denies the allegations in Counts One through Seven.

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i. Respondent hereby declares, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to best of my knowledge.

Dated this 27th day of January 2026.

Ivan Goldsmith MD

DocuSigned by: 4ZX8JW2Q-4Q6QZ878

Ivan Goldsmith, MD

CLARK HILL PLC

By */s/ Crane Pomerantz*
Crane M. Pomerantz
Nevada Bar No. 14103
Forrest M. Zimmerman
Nevada Bar No. 17017
1700 S. Pavilion Center Drive, Suite 500
Las Vegas, Nevada 89135

Attorneys for Respondent

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of Clark Hill PLC, and that on the 27th day of January 2026, I caused to be served a true and correct copy of the foregoing **Answer and Notice of Defense** in the following manner:

The above-referenced document was emailed to the Board's coordinating staff and its prosecuting attorney at the following addresses: TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov.

/s/ Jamie Soquena

An Employee of CLARK HILL PLC

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **IVAN LEE GOLDSMITH, MD,** **Certificate of Registration No. CS33713,** **Respondent.**	**Case No. 24-488-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Ivan Lee Goldsmith, MD, Certificate of Registration No. CS33713, by and through counsel, Crane M. Pomerantz, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about January 7, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about January 27, 2026, Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with

the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. By failing to timely renew his Certificate of Registration CS33713 prior to issuing controlled substance prescriptions, and by issuing controlled substance prescriptions without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated 21 U.S.C. § 822(a)(2) and (e)(1), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 C.F.R. § 1301.12, 21 CFR § 1306.03(a)(1), NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1);

B. By failing to review patient utilization reports in the Prescription Monitoring Program (PMP) database prior to issuing controlled substance prescriptions, Respondent violated NRS 639.23507; and

C. By his acts and omissions, Respondent has engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i) and (k), and committed acts that render his registration inconsistent with the public interest.

7. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210 and/or NRS 639.255.

8. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The certificate of registration of Ivan Lee Goldsmith, MD, Certificate of Registration No. CS33713, is

suspended for a period of one (1) year pursuant to NRS 453.241(1)(a). The suspension is stayed, and Respondent is placed on probation pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a practitioner under NRS Chapters 453, 454 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by May 1, 2026;

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by May 1, 2026;

D. Respondent shall complete training from Board staff on use of the PMP database in compliance with NRS 453.164(7) and NRS 639.23507 within sixty (60) days of the effective date of this Order and shall complete follow-up training six (6) months after the initial training; and

E. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS33713 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately suspend Respondent's Certificate of Registration No. CS33713 and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order,

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 29th day of January 2026

IVAN LEE GOLDSMITH, MD
Certificate of Registration No. CS33713

Signed this ___ day of _____ 2026

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 30th day of January 2026

CRANE M. POMERATZ, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Ivan Lee Goldsmith, MD, Certificate of Registration No. CS33713, in Case No. 24-488-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SOUTHWEST DME, INC.,** **License No. MP03145,** **Respondent.**	**CASE NO. 25-143-MP-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Southwest DME, Inc., License No. MP03145, was a medical products provider licensed by the Board to operate a facility located at 1516 E Tropicana Avenue - Suite 105 in Las Vegas, Nevada.

FACTUAL ALLEGATIONS

2. On or about February 20, 2025, the Board conducted an inspection of Respondent's facility and determined that Juliet Ramos, the administrator and owner on record with the Board, was no longer the owner or administrator, that Syed Moinuddin was the owner since September 2024, and that Respondent had operated without an administrator since September 2024.

3. Respondent failed to apply with the Board for a new license within 5 days after the completion of the transaction which changed the controlling interest and not operate the business until the new owner was licensed by the Board.

4. Respondent failed to notify the Board of the departure of its administrator within three (3) business days and continued to operate as a medical products provider for more than ten (10) business days without an administrator approved by the Board.

5. The inspection also revealed that Respondent had not maintained records required by law or maintained the required liability insurance.

APPLICABLE LAW

6. Any person who engages in the business of furnishing medical devices that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter. NRS 639.233(1).

7. Upon a change in the controlling interest of a licensed medical products provider, the medical products provider shall apply with the Board for a new license within 5 days after the completion of the transaction which changes the controlling interest and not operate the business, except to service, maintain, repair or otherwise satisfy the outstanding obligations of the predecessor business, until the new owner is licensed by the Board. NAC 639.6947.

8. Each licensed medical products provider shall employ an administrator approved by the Board, shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment, and may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator. NAC 639.694.

9. Each licensed medical products provider shall comply with the recordkeeping requirements of NAC 639.4946-.6956, *inclusive*, and maintain liability insurance of at least $1,000,000.

10. Performing any duties as the owner of a business or an entity licensed by the Board or as the employee of any such business in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

11. Violating any law or regulation relating to the practices of a medical products provider pursuant to NAC 639.6941(1)(a), and failing to maintain the required liability insurance pursuant to NAC 639.6941(1)(b) constitutes unprofessional conduct or conduct contrary to the

public interest and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

12. The Board may suspend or revoke a license if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any provision of Chapter 639 of the Nevada Revised Statutes. NRS 639.210(12).

COUNT ONE

Violation of State Law – Unlawful Operation Upon Change of Ownership

13. Respondent violated NAC 639.6947 by failing to apply with the Board for a new license within 5 days after the completion of the transaction which changed the controlling interest and not operating the business until the new owner was licensed by the Board, as alleged herein, and is subject to discipline pursuant to NRS 639.210(12).

COUNT TWO

Violation of State Law - Unlawful Operation Without Administrator

14. Respondent violated NAC 639.694 by failing to notify the Board of the departure of its administrator within three (3) business days and continued to operate as a medical products provider for more than ten (10) business days without an administrator approved by the Board, as alleged herein, and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Violation of State Law – Recordkeeping and Liability Insurance

15. Respondent violated NAC 639.4946-.6956, *inclusive*, by failing to maintain required records and liability insurance of at least $1,000,000, as alleged herein, and is subject to discipline pursuant to NRS 639.210(12).

COUNT FOUR

Unprofessional Conduct

16. By the violations as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i) and/or NAC 639.6941(1)(a) and/or (b), and is subject to discipline pursuant to NRS 639.210(4).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license of this respondent.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SOUTHWEST DME, INC.,** **License No. MP03145,** **Respondent.**	**Case No. 25-143-MP-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SOUTHWEST DME, INC.,** **License No. MP03145,** **Respondent.**	**Case No. 25-143-MP-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR SOUTHWEST DME, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of January 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

SouthwestDME, Inc.
1516 E Tropicana Ave Suite 105
Las Vegas NV 89119

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARIKA LENEE KERR, APRN,** **Certificate of Registration No. CS26747,** **Respondent.**	**CASE NO. 25-146-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Marika Lenee Kerr, APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS26747, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent has prior discipline from the Board in case no. 17-118-CS-S for permitting non-practitioners to unlawfully access, possess and administer dangerous drugs to patients without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship.

3. Respondent was engaged in practice at Carolina Skin Care, located at 9484 W Flamingo Rd. in Las Vegas, during the relevant times frame herein.

4. Carolina Molina owns and operates Carolina Skin Care and is not a Nevada-licensed practitioner.

5. On or about April 16, 2025, a Board investigator in the course of an on-site investigation at Carolina Skin Care determined that Respondent permitted Molina to use Respondent's credentials as a Nevada-licensed practitioner to purchase dangerous drugs, to maintain an unsecured inventory of dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.

6. Respondent permitted Molina to independently access, possess, furnish and administer dangerous drugs to patients, and to provide on-site medical treatment at Carolina Skin Care, including the administration of dangerous drugs by injection, and including, without limitation, glutathione, lipotropics, semaglutides, neuromodulators and dermal fillers, without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

7. Respondent regularly issued prescriptions for dangerous drugs falsely identifying Molina and other individuals as the patient to Meta Pharmacy Services, located at 8352 W. Warm Springs Road in Las Vegas, in order to obtain those drugs for office administration to multiple patients, and administered and/or permitted the administration of patient-specific prescription medications to multiple patients.

8. Respondent failed to keep and maintain complete, accurate and readily retrievable records accounting for all patients and dangerous drugs.

APPLICABLE LAW

9. No person may possess or administer a dangerous drug in Nevada, including administration by injection, without specific statutory authority to do so. NRS 200.840(1); NRS 454.213; NRS 454.217; NRS 454.221; NRS 454.316; NRS 454.321; NRS 454.356; NRS 454.510; NRS 639.100(1).

10. All controlled substances and dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

11. The Board may suspend or revoke the certificate of registration of an advanced practice registered nurse that has failed to maintain the security of his or her drug supply. NAC 639.900(12).

12. A practitioner may prescribe a dangerous drug for a specific patient in conformance with NRS 454.223 and NRS 639.2353.

13. It is a felony offense to sell or administer a misbranded or adulterated drug. NRS 585.520; NAC 639.601(1).

14. It is a felony offense to falsify a prescription for a dangerous drug or obtain a dangerous drug by a fraudulent prescription. NRS 454.311.

15. It is a felony offense for an unlicensed person to sell, display or offer for sale a prescription drug. NRS 639.285.

16. A practitioner may purchase supplies of dangerous drugs from a pharmacy, and a pharmacy may sell a dangerous drug to a practitioner who will be administering the drug to a patient; the quantity must not exceed the amount necessary for the practitioner to serve the present needs of the patients of the practitioner. NRS 639.268(1)(a) and NAC 639.757(4) and (5).

17. A practitioner shall keep and maintain complete, accurate and readily retrievable records accounting for all patients and dangerous drugs; NRS 454.286; NRS 629.051.

18. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

19. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

20. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

21. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

22. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454,585 or 639 of NRS or any regulation pertaining thereto, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

23. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

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COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

24. By permitting Molina to use Respondent's credentials as a Nevada-licensed practitioner to purchase dangerous drugs, to maintain an unsecured inventory of dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision, as alleged in paragraph 5 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213 and/or NAC 639.898(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(12) and/or (14) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

25. By permitting Molina to independently access, possess, furnish and administer dangerous drugs to patients, and to provide on-site medical treatment at Carolina Skin Care, including the administration of dangerous drugs by injection, and including, without limitation, glutathione, lipotropics, semaglutides, neuromodulators and dermal fillers, as alleged in paragraph 6 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 200.840(1), NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.510, NRS 639.100(1) and/or NRS 639.285, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(14) and/or NRS 639.210(12).

COUNT THREE

Violations of State Law - Issuing Fraudulent Prescriptions

26. By issuing prescriptions for dangerous drugs to Meta Pharmacy Services falsely identifying Molina and other individuals as the patient in order to obtain those drugs for office administration to multiple patients, as alleged in paragraph 7 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.311(1), NRS 454.316(2), NRS 639.2353, NRS 639.268(1)(a) and/or NAC 639.757(4)

and (5), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NAC 639.900(14) and/or NRS 639.210(12).

COUNT FOUR

Violation of State Law - Administration of Patient-Specific Prescription Medications to Multiple Patients

24. By permitting the administration of patient-specific prescription medications to multiple patients, as alleged in paragraph 7 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.221(1), NRS 585.520(1) and/or (2) and/or NAC 639.601(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(14) and/or NRS 639.210(12).

COUNT FIVE

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

25. By her conduct as alleged in paragraphs 5 and 6 herein, Respondent was party to a fraudulent or deceitful practice or transaction, performed her duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, aided and abetted Molina in unlicensed practice, and engaged in, or aided and abetted Molina to engage in, unprofessional conduct as defined in NAC 639.945(h), (i), (j) and (n)(1), and Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(4) and/or NRS 639.210(12).

COUNT SIX

Unprofessional Conduct - Issuing Fraudulent Prescriptions

26. By issuing prescriptions for dangerous drugs to Meta Pharmacy Services falsely identifying Molina and other individuals as the patient in order to obtain those drugs for office administration to multiple patients, and permitting the administration of patient-specific prescription medications to multiple patients, as alleged in paragraph 7 herein, Respondent was party to a fraudulent or deceitful practice or transaction, performed her duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC

639.945(1)(h) and (i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(4) and/or NRS 639.210(12).

COUNT SEVEN

Violations of State Law - Recordkeeping

27. By failing to keep and maintain complete, accurate and readily retrievable records accounting for all patients and dangerous drugs as alleged in paragraph 8 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.286 and/or NAC 629.051, and is therefore subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(14) and/or NRS 639.210(12).

COUNT EIGHT

Commission of Acts that Render Registration Inconsistent with the Public Interest

28. By her acts as alleged herein, Respondent has committed acts that render her registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARIKA LENEE KERR, APRN,** **Certificate of Registration No. CS26747,** **Respondent.**	**Case No. 25-146-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARIKA LENEE KERR, APRN,** **Certificate of Registration No. CS26747,** **Respondent.**	**Case No. 25-146-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

MARIKA LENEE KERR, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of January 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Marika Kerr
[redacted]
Las Vegas, NV [redacted]

Marika Kerr
c/o Roseman University
11 Sunset Way
Henderson, NV 89014

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

5G

FILED
JUL 25 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 25-215-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

FACTUAL ALLEGATIONS

1. On or about May 5, 2025, in *United States of America v. Festus Onymaliosia Ebonka*, United States District Court for the District of Nevada, Case No. 2:22-cr-00156-CDS-NJK-1, Respondent pled guilty to and was convicted on one misdemeanor count of conversion of government property, in violation of 18 U.S. Code § 641.

2. The conviction resulted from Respondent falsely billing Medicaid for services that Respondent did not personally provide, and received reimbursement for those services.

APPLICABLE LAW

3. Medicaid fraud is a felony offense under State law. NRS 422.540(1).

4. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

5. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

6. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. Conviction of a crime involving moral turpitude, dishonesty or corruption is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(7)(c).

COUNT ONE

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

8. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(h) and is therefore subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

4. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT THREE

Criminal Conviction for Conversion of Government Property

9. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, an act that also constitute a felony offense under NRS 422.540(1), Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or 639.210(7)(c).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

10. By his federal conviction on one criminal count of conversion of government property for falsely billing Medicaid for services that Respondent did not personally provide, and receiving reimbursement for those services, an act that also constitute a felony offense under NRS 422.540(1), Respondent has committed acts that render his Nevada controlled substance registration inconsistent with the public interest, and is therefore subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 25th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 25-215-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. A **hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 25-215-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Festus Ebonka, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Festus Ebonka
[redacted]
Las Vegas, NV [redacted]

Nevada Treatment Center
c/o Festus Ebonka
1721 E Charleston Blvd
Las Vegas, NV 89104

Liborius Agwara, Esq.
2785 E Desert Inn Rd, Ste 270
Las Vegas, NV 89121

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
SEP 03 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. **FESTUS EBONKA, APRN,** Certificate of Registration No. CS23430 Respondent.	**Case No. 25-215-CS-S**

ANSWER AND NOTICE OF DEFENSE

Respondent, **FESTUS EBONKA, APRN,** by and through counsel, LIBORIUS AGWARA, ESQ., of the Law Offices of Libo Agwara, Ltd., hereby files his Answer and Notice of Defense to THE NEVADA STATE BOARD OF PHARMACY'S ("Board") Complaint and states as follows:

1. Answering Paragraphs 1, 1, and 2, Respondent admits the allegations contained therein.

2. Answering Paragraphs 2, 8, 4, 9, and 10, Respondent denies the allegations contained therein.

3. Answering Paragraphs 3, 4, 5, 6, and 7, Respondent states that he is without sufficient knowledge as to the truth or falsity of the allegations contained therein, and as such denies them.

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2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

WHEREFORE, Respondent, respectfully requests that the Board find that he did not violate the Control Substance Act. Respondent further requests such other and additional relief as the Board may deem just and proper under the circumstances.

Dated this 3rd day of September 2025.

LAW OFFICES OF LIBO AGWARA, LTD

LIBORIUS AGWARA, ESQ.
Nevada Bar No.: 7576
2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
Tel: (702) 385-4800 Phone
Libolaw@yahoo.com
Attorney for Respondent

2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

VERIFICATION

STATE OF NEVADA)
) ss.
COUNTY OF CLARK)

I, FESTUS EBONKA, under penalties of perjury, being first duly sworn, deposes and says:

That I am the Respondent in the above-entitled action; that I have read the foregoing ANSWER AND NOTICE OF DEFENSE and know the contents thereof; that the same is true of my own knowledge, except for those matters therein contained stated upon information and belief, and as to those matters, I believe them to be true.

DATED this 2nd day of September 2025.

FESTUS EBONKA

2785 E. Desert Inn Rd., Ste. 270
Las Vegas, NV 89121
702-385-4800 Phone

SEALED

Office of the United States Attorney
District of Nevada
501 Las Vegas Boulevard, Suite 1100
Las Vegas, Nevada 89101
(702) 388-6336

FILED ENTERED RECEIVED SERVED ON COUNSEL/PARTIES OF RECORD
JUL 19 2022
CLERK US DISTRICT COURT DISTRICT OF NEVADA
BY: DEPUTY

JASON M. FRIERSON
United States Attorney
Nevada Bar Number 7709
RICHARD ANTHONY LOPEZ
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Las Vegas, Nevada 89101
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tony.lopez@usdoj.gov
Attorneys for the United States

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

UNITED STATES OF AMERICA,

Plaintiff,

v.

FESTUS ONYEMALIOSIA EBONKA,

Defendant.

SEALED
CRIMINAL INDICTMENT

Case No. 2:22-cr-156 CDS NJK

VIOLATION:

Health Care Fraud (18 U.S.C. § 1347)

THE GRAND JURY CHARGES THAT:

Introductory Allegations

At times material to this Indictment:

1. Defendant FESTUS ONYEMALIOSIA EBONKA, a resident of Las Vegas, Nevada, was a registered nurse and a certified nurse practitioner licensed to practice in Nevada. EBONKA was a Medicare provider and was required to abide by all Medicare rules and regulations.

2. EBONKA owned and operated three Nevada companies (collectively, "the Ebonka Entities") enrolled in the Medicare program: Nevada Integrated Behavioral Services Inc.; Ebonny Behavioral Care Services Corporation; and CBH Wellness Clinic, Inc.

3. D.B., E.G., Ge.A., Gw.A., J.G., K.K., Mi.H., My.H., T.H., and Y.H. were Medicare beneficiaries residing in the District of Nevada.

4. E.H., J.L., and L.S. were former Medicare beneficiaries who were deceased.

The Medicare Program

5. The Medicare program ("Medicare") was a federal health care program, as defined in Title 18, United States Code, Section 24(b), that provided free or below cost health care benefits to certain eligible beneficiaries, primarily persons who were 65 years of age or older or disabled. The Centers for Medicare and Medicaid Services (CMS), a federal agency within the U.S. Department of Health and Human Services, administers the Medicare program.

6. Medicare was divided into four parts and covered specific benefits, items, and services: hospital insurance (Part A), medical insurance (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D).

7. Medicare Part B covered outpatient physician and non-physician practitioner services, durable medical equipment, and some preventive services.

8. Physicians, nurses, nurse practitioners, clinics, laboratories, and other health care providers that provided services to Medicare beneficiaries were able to apply for and obtain a "provider number." A health care provider that received a Medicare provider number was able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

9. To receive Medicare reimbursement, providers had to fill out an application and execute a written provider agreement, known as CMS Form 855. The application contained certifications that the provider agreed to abide by Medicare laws and regulations, and that the provider "[would] not knowingly present or cause to be presented a false or

fraudulent claim for payment by Medicare, and [would] not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." Medicare providers were given access to Medicare manuals and service bulletins describing procedures, rules, and regulations.

HCPCS Code L8679

10. CMS established the Healthcare Common Procedure and Coding System (HCPCS) Level II Code Set. The HCPCS Level II Code Set is a standardized five-digit alphanumeric coding system that is used by federal, state, and private health insurance entities primarily to identify products, supplies, and services provided by healthcare professionals. These codes are also used to bill and submit claims to federal, state, and private insurance entities for reimbursement of medical services provided to beneficiaries. The coding system adheres to the following format: the first digit is a letter that identifies the HCPCS code chapter and payment category that the service belongs to and group similar services together, while the last four digits are numeric characters. For example, codes beginning with an "L" belong to the prosthetics and orthotics services/payment category.

11. HCPCS code L8679 is used to bill for Medicare-covered neurostimulator devices that require surgical implantation. The use of a neurostimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver which is implanted under the skin at a depth not greater than ½ inch. Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of the stimulating electrodes requires a surgical process that takes at least one to two hours and usually necessitates an operating room.

The Stivax Device

12. Stivax is a medical device placed on the top of a patient's inner ear, has a battery, and stays on for about two weeks. The Food and Drug Administration describes Stivax as a single use, battery-powered, electrical nerve stimulator which is used for the stimulation of the vagus nerve through the ear. The stimulator is taped to the patient's ear. The FDA stated that the Stivax device is indicated for use as an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners as determined by the states. Medicare does not provide reimbursement for acupuncture services, such as the provision and use of the Stivax device.

COUNTS ONE TO THIRTEEN
Health Care Fraud
(18 U.S.C. § 1347)

13. Beginning in or around March 2017, and continuing through in or around September 2018, within the State and Federal District of Nevada and elsewhere,

FESTUS ONYEMALIOSIA EBONKA,

defendant herein, knowingly and willfully executed, attempted to execute, and participated in a scheme and artifice to defraud a health care benefit program, namely Medicare, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, a health care benefit program, in connection with the delivery of, and payment for, health care benefits, items, and services, as described below.

14. The purpose of the scheme and artifice to defraud was for EBONKA to unlawfully enrich himself by causing the submission of materially false and fraudulent claims to Medicare through the Ebonka Entities.

15. It was part of the scheme that EBONKA submitted and caused to be submitted false and fraudulent claims requesting reimbursement under Procedure Code L8679 that were ineligible for Medicare reimbursement.

16. These claims were false and fraudulent in that EBONKA and the Ebonka Entities had not provided medical services that qualified for reimbursement under Procedure Code L8679, including, for example:

a. Claims in the name of beneficiaries who received services related to the Stivax device, which did not qualify for any Medicare reimbursement, on the date indicated on the claim.

b. Claims in the name of beneficiaries who received no services related to the Stivax device on the date indicated on the claim.

c. Claims in the names of beneficiaries who were deceased at the time EBONKA purportedly provided them with medical services.

17. From in or around March 2017 through in or around September 2018, EBONKA caused the submission to Medicare of at least 2,500 false and fraudulent claims requesting at least $25 million in reimbursement. Medicare paid the Ebonka Entities more than $10 million as a result of EBONKA's fraudulent claim submissions.

18. On or about the dates set forth below, within the State and Federal District of Nevada and elsewhere, EBONKA did knowingly and willfully execute, attempt to execute, and participate in the above-described scheme and artifice in that EBONKA caused the submission of the false and fraudulent claims described below to Medicare seeking reimbursement for the approximate amount of $10,000 per claim, each submission a separate violation of 18 U.S.C. § 1347:

COUNT	DATE	BENEFICIARY	CLAIM ID NUMBER
ONE	7/26/2017	My.H.	332217226279930
TWO	7/26/2017	Y.H.	332217226279900
THREE	11/30/2017	Ge.A.	332217334233980
FOUR	12/4/2017	J.L.	332217338272650
FIVE	1/2/2018	L.S.	332218002134640
SIX	1/15/2018	E.G.	332218015227810
SEVEN	1/16/2018	J.G.	332218016244790
EIGHT	8/29/2018	Gw.A.	332218241165940
NINE	8/31/2018	Mi.H.	332218243184230
TEN	9/4/2018	E.H.	332218247168190
ELEVEN	9/4/2018	K.K.	332218247167770
TWELVE	9/5/2018	T.H.	332218248189290
THIRTEEN	9/7/2018	D.B.	338518250351150

DATED this 19th day of July, 2022.

A TRUE BILL:

/S/
FOREPERSON OF THE GRAND JURY

JASON M. FRIERSON
United States Attorney

RICHARD ANTHONY LOPEZ
Assistant United States Attorney

SUE FAHAMI
Acting United States Attorney
District of Nevada
Nevada Bar Number 5634
RICHARD ANTHONY LOPEZ
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Las Vegas, Nevada 89101
Tel: (702) 388-6336
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Attorneys for the United States

FILED
ENTERED
RECEIVED
SERVED ON
COUNSEL/PARTIES OF RECORD
FEB 04 2025
CLERK US DISTRICT COURT
DISTRICT OF NEVADA
BY: DEPUTY

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

UNITED STATES OF AMERICA,

Plaintiff,

v.

FESTUS ONYEMALIOSIA EBONKA,

Defendant.

No. 2:22-cr-00156-CDS-NJK

Plea Agreement for Defendant Festus Onyemaliosia Ebonka Pursuant to Fed. R. Crim. P. 11(c)(1)(A) and (B)

This plea agreement between Festus Onyemaliosia Ebonka ("defendant") and the United States Attorney's Office for the District of Nevada (the "USAO") sets forth the parties' agreement regarding the criminal charges referenced herein and the applicable sentences, fines, and restitution in the above-captioned case. This agreement binds only defendant and the USAO and does not bind the district court, the U.S. Probation Office, or any other federal, state, local, or foreign prosecuting, enforcement, administrative, or regulatory authorities. This agreement does not prohibit the USAO or any agency or third party from seeking any other civil or administrative remedies, including administrative forfeiture or civil forfeiture *in rem* actions, directly or indirectly against defendant or defendant's property.

This agreement becomes effective upon signature by defendant, defendant's counsel, and an Assistant United States Attorney.

I. DEFENDANT'S OBLIGATIONS

1. Defendant agrees to:

a. Give up the right to indictment by a grand jury and, at the earliest opportunity requested by the USAO and provided by the Court, appear and plead guilty to a one-count information in the form attached to this agreement as Exhibit A or a substantially similar form, which charges defendant with Conversion of Government Money, a Class A misdemeanor, in violation of 18 U.S.C. § 641.

b. Stipulate to the facts agreed to in this agreement;

c. Abide by all agreements regarding sentencing contained in this agreement;

d. Not seek to withdraw defendant's guilty pleas once it is entered;

e. Appear for all court appearances, surrender as ordered for service of sentence, obey all conditions of any bond, and obey any other ongoing court order in this matter;

f. Not commit any federal, state, or local crime;

g. Be truthful at all times with the U.S. Probation and Pretrial Services Offices and the Court;

h. Before and after sentencing, upon request by the Court, the USAO, or the Probation Office, provide accurate and complete financial information, submit sworn statements, and/or give depositions under oath concerning defendant's assets and defendant's ability to pay. As part of the required disclosure, defendant agrees to provide any and all financial information and authorizations requested by the Probation Office for preparation of the Presentence Report. Defendant further agrees that, upon filing of this agreement, the USAO is authorized to obtain defendant's credit report. Defendant will also complete a financial form

provided by the USAO, to include all supporting documentation, and return it to the USAO within ten (10) days from entry of the plea. Defendant agrees that the district court may enter any order necessary to effectuate or facilitate disclosure of defendant's financial information;

i. To facilitate payment of any fine, restitution, or assessment, surrender assets defendant obtained directly or indirectly as a result of defendant's crimes. Defendant agrees to voluntarily release funds and property under defendant's control or in which defendant has any property interest, before and after sentencing, to pay any fine or restitution identified in this agreement, agreed to by the parties, or ordered by the Court;

j. Defendant agrees that restitution shall be ordered due and payable in full immediately after the judgment is entered, and that the full amount of any restitution ordered is subject to immediate enforcement and collection by the USAO or defendant's victims, or both. Defendant agrees that any schedule of payments entered by the district court is a schedule of the minimum payment due and does not prohibit or limit the methods by which the USAO may immediately enforce and collect the judgment in full. Defendant acknowledges that restitution may not be discharged, in whole or in part, in any present or future bankruptcy proceeding.

II. THE USAO'S OBLIGATIONS

2. The USAO agrees to:

a. Stipulate to facts agreed to in this agreement;

b. Abide by all agreements regarding sentencing contained in this agreement;

c. At sentencing, provided that defendant demonstrates an acceptance of responsibility for the offenses up to and including the time of sentencing, recommend a two-level reduction in the applicable sentencing guidelines offense level, pursuant to USSG § 3E1.1;

d. At sentencing, move to dismiss the indictment against defendant. Defendant agrees, however, that the district court may consider any dismissed charges in

determining the applicable sentencing guidelines range, the propriety and extent of any departure from that range, and the sentence to be imposed; and

e. Not bring any additional charges against defendant arising out of the factual basis set forth in this agreement. However, the USAO reserves the right to prosecute defendant for (a) any crime of violence as defined by 18 U.S.C. § 16; and (b) any criminal tax violations (including conspiracy to commit such violations chargeable under 18 U.S.C. § 371). Defendant agrees that the district court at sentencing may consider any uncharged conduct in determining the applicable sentencing guidelines range, the propriety and extent of any departure from that range, and the sentence to be imposed after consideration of the sentencing guidelines and all other relevant factors under 18 U.S.C. § 3553(a).

III. ELEMENTS OF THE OFFENSE

3. Count One: The elements of Conversion of Government Money under 18 U.S.C. § 641 are as follows:

First: The defendant knowingly converted to the defendant's use money with the intention of depriving the owner of the use or benefit of the money; and

Second: the money belonged to the United States.

See Ninth Circuit Model Criminal Jury Instruction 23.1 (2022 ed.).

4. Deliberate Indifference: A defendant acts knowingly if:

First: The defendant was aware of a high probability that he was not entitled to reimbursement by Medicare, and

Second: the defendant deliberately avoided learning the truth.

See Ninth Circuit Model Criminal Jury Instruction 4.9 (2022 ed.).

IV. CONSEQUENCES OF CONVICTION

5. Maximum Statutory Penalties: Defendant understands that the statutory maximum sentence the district court can impose for a violation of 18 U.S.C. § 641 as charged in the Information, is: one year of imprisonment; a one-year period of supervised release; a fine of $250,000 or twice the gross gain or gross loss resulting from the offense, whichever is greatest; and a mandatory special assessment of $25.

6. Restitution: Defendant understands that defendant will be required to pay full restitution to the victim(s) of the offense to which defendant is pleading guilty. The parties currently believe that the applicable amount of restitution is approximately $6,519.69, but recognize and agree that this amount could change based on facts that come to the attention of the parties prior to sentencing.

7. Parole Abolished: Defendant acknowledges that defendant's prison sentence cannot be shortened by early release on parole because parole has been abolished.

8. Supervised Release: Defendant understands that supervised release is a period of time following imprisonment during which defendant will be subject to various restrictions and requirements. Defendant understands that if defendant violates one or more of the conditions of any supervised release imposed, defendant may be returned to prison for all or part of the term of supervised release authorized by statute for the offense that resulted in the term of supervised release, which could result in defendant serving a total term of imprisonment greater than the statutory maximum stated above.

9. Factors under 18 U.S.C. § 3553: Defendant understands that the district court must consider the factors set forth in 18 U.S.C. § 3553(a) in determining defendant's sentence. However, the statutory maximum sentence limits the district court's discretion in determining defendant's sentence.

10. Potential Collateral Consequences of Conviction: Defendant understands that, by pleading guilty, defendant may be giving up valuable government benefits and valuable civic rights. Defendant understands that the conviction in this case may subject defendant to various other collateral consequences, including but not limited to revocation of probation, parole, or supervised release in another case and suspension or revocation of a professional license. Defendant understands that unanticipated collateral consequences will not serve as grounds to withdraw defendant's guilty plea.

11. Potential Removal/Deportation Consequences of Conviction: Defendant understands that, if defendant is not a United States citizen, the conviction in this case may subject defendant to removal, also known as deportation, which may, under some circumstances, be mandatory; denial of citizenship; and denial of admission to the United States in the future. The district court cannot advise defendant fully regarding the immigration consequences of the conviction in this case, but defendant's attorney has advised him about the deportation risks of his guilty plea. Defendant understands that unexpected immigration consequences will not serve as grounds to withdraw defendant's guilty plea.

V. FACTUAL BASIS

12. Defendant admits that defendant is, in fact, guilty of the offense to which defendant is agreeing to plead guilty. Defendant acknowledges that if defendant elected to go to trial instead of pleading guilty, the USAO could prove defendant's guilt beyond a reasonable doubt. Defendant further acknowledges that defendant's admissions and declarations of fact set forth below satisfy every element of the charged offense. Defendant waives any potential future claim that the facts defendant admitted below are insufficient to satisfy the elements of the charged offense. Defendant admits and declares under penalty of perjury that the facts set forth below are true and correct:

a. At all relevant times, defendant Festus Onyemaliosia Ebonka, a resident of Las Vegas, Nevada, was a registered nurse and a certified nurse practitioner licensed to practice in Nevada. Ebonka was a provider enrolled in Medicare and was required to abide by all Medicare rules and regulations.

b. From in or around March 2017 through in or around September 2018, Ebonka, through businesses under his control, caused the submission to Medicare of claims requesting reimbursement under Procedure Code L8679.

c. Ebonka submitted those claims based on the purported application of a device called Stivax to patients covered by Medicare.

d. However, these claims were false because Procedure Code L8679 does not cover the application of the Stivax device, which Medicare considers a non-reimbursement acupuncture treatment.

e. On September 13, 2018, Ebonka caused the submission to Medicare of a request for $10,000 of reimbursement under Procedure Code L8679 for services rendered to B.A., a patient of Ebonka. The claim was false because the services provide to B.A. – the application of the Stivax device – were not covered by Procedure Code L8679. Based on this clam, Medicare, a federal agency, reimbursed Ebonka $6,519.69, which he converted to his own use.

f. At the time Ebonka caused the above submission for services provided to B.A., he was deliberately ignorant to the false nature of this claim, that is, he was aware of a high probability that Procedure Code L8679 did not cover the application of the Stivax device and deliberately avoided learning the truth.

g. All of the above occurred in the District of Nevada and elsewhere.

VI. SENTENCING FACTORS

13. Discretionary Nature of Sentencing Guidelines: Defendant understands that in determining defendant's sentence, the district court is required to calculate the applicable sentencing guidelines range and to consider that range, possible departures under the sentencing guidelines, and the other sentencing factors set forth in 18 U.S.C. § 3553(a). Defendant understands that the sentencing guidelines are advisory only, that defendant cannot have any expectation of receiving a sentence within the calculated sentencing guidelines range, and that after considering the sentencing guidelines and the other § 3553(a) factors, the district court will be free to exercise its discretion to impose any sentence it finds appropriate up to the maximum set by statute for the crime of conviction.

14. Offense Level Calculations: The parties jointly agree and stipulate that, in calculating defendant's advisory guidelines sentencing range, the district court should use the following base offense level and adjustments; acknowledge that these stipulations do not bind the district court; and agree that they will not seek to apply or advocate for the use of any other base offense level(s) or any other specific offense characteristics, enhancements, or reductions in calculating the advisory guidelines range:

Base Offense Level [USSG § 2B1.1(a)(2)]:	6
Loss Exceeds $6,500 [USSG § 2B1.1(b)(1)(B)]:	+2
Adjusted Offense Level:	8

The parties further agree that, if, at the time of sentencing, the district court determines that defendant has not received any criminal history points from Chapter Four, Part A, the parties will jointly recommend that defendant receive a two-level reduction pursuant to § 4C1.1(a).

15. Reduction for Acceptance of Responsibility: Under USSG § 3E1.1(a), the USAO will recommend that defendant receive a two-level downward adjustment for acceptance of

responsibility unless defendant (a) fails to truthfully admit facts establishing a factual basis for the guilty plea when defendant enters the plea; (b) fails to truthfully admit facts establishing the amount of restitution owed when defendant enters the guilty plea; (c) fails to truthfully admit facts establishing the forfeiture allegations when defendant enters the guilty plea; (d) provides false or misleading information to the USAO, the Court, Pretrial Services, or the Probation Office; (e) denies involvement in the offense or provides conflicting statements regarding defendant's involvement or falsely denies or frivolously contests conduct relevant to the offense; (f) attempts to withdraw defendant's guilty plea; (g) commits or attempts to commit any crime; (h) fails to appear in court; or (i) violates the conditions of pretrial release.

16. Criminal History Category: Defendant acknowledges that the district court may base defendant's sentence in part on defendant's criminal record or criminal history. The district court will determine defendant's criminal history category under the sentencing guidelines.

17. Additional Sentencing Information: The stipulated sentencing guidelines calculations are based on information now known to the parties. Defendant understands that both defendant and the USAO are free to (a) supplement the facts in this agreement by supplying relevant information to the U.S. Probation and Pretrial Services Offices and the district court regarding the nature, scope, and extent of defendant's criminal conduct and any aggravating or mitigating facts or circumstances; and (b) correct any and all factual misstatements relating to the district court's sentencing guidelines calculations and determination of sentence. While this paragraph permits both the USAO and defendant to submit full and complete factual information to the U.S. Probation and Pretrial Services Offices and the district court, even if that factual information may be viewed as inconsistent with the facts agreed to in this agreement, this paragraph does not affect defendant's and the USAO's obligations not to contest the facts agreed

to in this agreement. Good faith efforts to provide truthful information or to correct factual misstatements shall not be grounds for defendant to withdraw defendant's guilty plea.

18. Defendant acknowledges that the U.S. Probation Office may calculate the sentencing guidelines differently and may rely on additional information it obtains through its investigation. Defendant also acknowledges that the district court may rely on this and other additional information as it calculates the sentencing guidelines range and makes other sentencing determinations, and the district court's reliance on such information shall not be grounds for defendant to withdraw defendant's guilty plea.

VII. POSITIONS REGARDING SENTENCING

19. The parties will jointly recommend that the district court sentence defendant to sentence of three years of probation. In the event that a sentence of three years of probation is outside defendant's advisory Guideline range as determined by the district court, the parties will jointly request a variance to three years of probation.

20. Defendant acknowledges that the district court does not have to follow the recommendation of either party.

21. Notwithstanding its agreement to recommend a sentence as described above, the USAO reserves its right to defend any lawfully imposed sentence on appeal or in any post-conviction litigation.

22. If defendant commits any act that results in the district court finding that defendant is not entitled to a downward adjustment for acceptance of responsibility, the USAO is entitled to argue for any sentence it deems appropriate under 18 U.S.C. § 3553(a). In any such event, Defendant remains bound by the provisions of this agreement and shall not have the right to withdraw defendant's guilty plea.

VIII. WAIVER OF CONSTITUTIONAL RIGHTS

23. Defendant understands that by pleading guilty, defendant gives up the following rights:

a. The right to persist in a plea of not guilty;

b. The right to a speedy and public trial by jury;

c. The right to be represented by counsel—and if necessary have the court appoint counsel—at trial. Defendant understands, however, that, defendant retains the right to be represented by counsel—and if necessary have the court appoint counsel—at every other stage of the proceeding;

d. The right to be presumed innocent and to have the burden of proof placed on the USAO to prove defendant guilty beyond a reasonable doubt;

e. The right to confront and cross-examine witnesses against defendant;

f. The right to testify and to present evidence in opposition to the charges, including the right to compel the attendance of witnesses to testify;

g. The right not to be compelled to testify, and, if defendant chose not to testify or present evidence, to have that choice not be used against defendant; and

h. The right to pursue any affirmative defenses; Fourth Amendment or Fifth Amendment claims; any other pretrial motions that have been or could have been filed; and challenges to any adverse pre-trial rulings (unless specifically reserved in the following section).

24. Having been fully advised by defendant's attorney regarding application of the statute of limitations to the offense to which defendant is pleading guilty, defendant hereby knowingly, voluntarily, and intelligently waives, relinquishes, and gives up: (a) any right that defendant might have not to be prosecuted for the offense to which defendant is pleading guilty because of the expiration of the statute of limitations for that offense prior to the filing of the

information alleging that offense; and (b) any defense, claim, or argument defendant could raise or assert that prosecution of the offense to which defendant is pleading guilty is barred by the expiration of the applicable statute of limitations, pre-indictment delay, or any speedy trial violation.

IX. WAIVER OF APPELLATE RIGHTS

25. Waiver of Appellate Rights: Defendant knowingly and expressly waives the right to appeal: (a) any sentence imposed within or below the applicable Sentencing Guideline range as determined by the district court; (b) the manner in which the district court determined that sentence on the grounds set forth in 18 U.S.C. § 3742; (c) any other aspect of the conviction, including but not limited to the constitutionality of the statutes of conviction; and (d) any other aspect of the sentence, including but not limited to the constitutionality of any mandatory or standard conditions of supervised release; the denial of any motion for early termination of supervised release; and any order of restitution or forfeiture.

26. Defendant reserves only the right to appeal any portion of the sentence that is an upward departure or variance from the applicable Sentencing Guideline range as determined by the district court.

27. Waiver of Post-Conviction Rights: Defendant also knowingly and expressly waives all collateral challenges, including any claims under 28 U.S.C. § 2255, to defendant's conviction, sentence, and the procedure by which the district court adjudicated guilt and imposed sentence, except non-waivable claims of ineffective assistance of counsel.

28. Preservation of Evidence: Defendant acknowledges that the USAO and the agencies investigating this case are not obligated or required to preserve any evidence obtained in the investigation of this case.

X. RESULT OF WITHDRAWAL OF GUILTY PLEA OR VACATUR/REVERSAL/SET-ASIDE OF CONVICTION

29. Consequence of Withdrawal of Guilty Plea: Defendant agrees that if, after entering a guilty plea pursuant to this agreement, defendant seeks to withdraw and succeeds in withdrawing defendant's guilty plea on any basis other than a claim and finding that entry into this agreement was involuntary, then (a) the USAO will be relieved of all of its obligations under this agreement and (b) should the USAO choose to pursue any that was either dismissed or not filed as a result of this agreement, or that the government agreed to move to dismiss at sentencing as part of this agreement, or that the government agreed to move to dismiss at sentencing as part of this agreement, then (i) any applicable statute of limitations will be tolled between the date of defendant's signing of this agreement and the filing commencing any such action; and (ii) defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

30. Consequence of Vacatur, Reversal, or Set-aside: Defendant agrees that if defendant's conviction is vacated, reversed, or set aside, both the USAO and defendant will be released from all their obligations under this agreement, except that, should the USAO choose to pursue any charge that was either dismissed or not filed as a result of this agreement, then (i) any applicable statute of limitations will be tolled between the date of defendant's signing of this agreement and the filing commencing any such action; and (ii) defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

XI. BREACH OF AGREEMENT

31. Defendant agrees that if, at any time after this agreement becomes effective, defendant knowingly violates or fails to perform any of defendant's obligations under this agreement ("a breach"), the USAO may declare this agreement breached. All of defendant's obligations are material, a single breach of this agreement is sufficient for the USAO to declare a breach, and defendant shall not be deemed to have cured a breach without the express agreement of the USAO in writing. If the USAO declares this agreement breached, and the district court finds such a breach to have occurred, then: (a) if defendant has previously entered a guilty plea pursuant to this agreement, defendant will remain bound by the provisions of this agreement and will not be able to withdraw the guilty plea; and (b) the USAO will be relieved of all its obligations under this agreement.

32. Following the Court's finding of a knowing breach of this agreement by defendant, should the USAO choose to pursue any charge that was either dismissed or not filed as a result of this agreement, or that the government agreed to move to dismiss at sentencing as part of this agreement, then:

a. Defendant agrees that any applicable statute of limitations is tolled between the date of defendant's signing of this agreement and the filing commencing any such action.

b. Defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

c. Defendant agrees that: (i) any statements made by defendant, under oath, at the guilty plea hearing (if such a hearing occurred prior to the breach); (ii) the agreed to factual basis statement in this agreement; and (iii) any evidence derived from such statements, shall be

admissible against defendant in any such action against defendant, and defendant waives and gives up any claim under the United States Constitution, any statute, Federal Rule of Evidence 410, Federal Rule of Criminal Procedure 11(f), or any other federal rule, that the statements or any evidence derived from the statements should be suppressed or are inadmissible.

XII. COURT AND UNITED STATES PROBATION AND PRETRIAL SERVICES OFFICE NOT PARTIES

33. Defendant understands that the Court and the U.S. Probation and Pretrial Services Office are not parties to this agreement and need not accept any of the USAO's sentencing recommendations or the parties' agreements to facts or sentencing factors.

34. Defendant understands that both defendant and the USAO are free to argue on appeal and collateral review that the district court's sentencing guidelines calculations and the sentence it chooses to impose are not error.

35. Defendant understands that even if the district court ignores any sentencing recommendation, finds facts or reaches conclusions different from those agreed to by the parties, or imposes any sentence up to the maximum established by statute, defendant cannot, for that reason, withdraw defendant's guilty plea[s], and defendant will remain bound to fulfill all defendant's obligations under this agreement. Defendant understands that no one—not the prosecutor, defendant's attorney, or the Court—can make a binding prediction or promise regarding the sentence defendant will receive, except that it will be within the statutory maximum.

XIII. ADDITIONAL ACKNOWLEDGMENTS

36. Defendant acknowledges that:

a. Defendant read this agreement, and defendant understands its terms and conditions.

b. Defendant had adequate time to discuss this case, the evidence, and this agreement with defendant's attorney.

c. Defendant carefully and thoroughly discussed all terms of this agreement with defendant's attorney.

d. Defendant understands the terms of this agreement and voluntarily agrees to those terms.

e. Defendant has discussed with defendant's attorney the following: the evidence; defendant's rights; possible pretrial motions that might be filed; possible defenses that might be asserted either prior to or at trial; the sentencing factors set forth in 18 U.S.C. § 3553(a); the relevant sentencing guidelines provisions; and consequences of entering into this agreement.

f. The representations contained in this agreement are true and correct, including the factual basis for defendant's offense set forth in this agreement.

g. Defendant was not under the influence of any alcohol, drug, or medicine that would impair defendant's ability to understand the agreement when defendant considered signing this agreement and when defendant signed it.

37. Defendant understands that defendant alone decides whether to plead guilty or go to trial, and acknowledges that defendant has decided to enter defendant's guilty plea knowing of the charges brought against defendant, defendant's possible defenses, and the benefits and possible detriments of proceeding to trial.

38. Defendant understands that no promises, understandings, or agreements other than those set forth in this agreement have been made or implied by defendant, defendant's attorney, or the USAO, and no additional promises, agreements, or conditions shall have any force or effect unless set forth in writing and signed by all parties or confirmed on the record before the district court.

39. Defendant acknowledges that defendant decided to plead guilty voluntarily and that no one threatened, coerced, or forced defendant to enter into this agreement.

40. Defendant is satisfied with the representation of defendant's attorney, and defendant is pleading guilty because defendant is guilty of the charges and chooses to take advantage of the promises set forth in this agreement and for no other reason.

XIV. PLEA AGREEMENT PART OF THE GUILTY PLEA HEARING

41. The parties agree that this agreement will be considered part of the record of defendant's guilty plea hearing as if the entire agreement had been read into the record of the proceeding.

AGREED AND ACCEPTED

UNITED STATES ATTORNEY'S OFFICE
FOR THE DISTRICT OF NEVADA

SUE FAHAMI
Acting United States Attorney

2.4.25

RICHARD ANTHONY LOPEZ
JESSICA OLIVA
Assistant United States Attorneys

Date

2/4/25

FESTUS ONYEMALIOSIA EBONKA
Defendant

Date

CRANE M. POMERANTZ, ESQ.
LIBORIUS AGWARA, ESQ.
Attorneys for Defendant EBONKA

Date

EXHIBIT A
Form of One-Count Information
Charging Defendant Ebonka

THE UNITED STATES ATTORNEY CHARGES THAT

COUNT ONE
Conversion of Government Property
(18 U.S.C. § 641)

On or about September 13, 2018, in the State and Federal District of Nevada,

FESTUS ONYEMALIOSIA EBONKA,

defendant herein, willfully and knowingly did convert to his own use money from Medicare, an agency of the United States, to which defendant knew he was not entitled, all in violation of Title 18, United States Code, Section 641.

UNITED STATES DISTRICT COURT

District of Nevada

UNITED STATES OF AMERICA
v.
FESTUS ONYEMALIOSIA EBONKA

JUDGMENT IN A CRIMINAL CASE

Case Number: 2:22-cr-00156-CDS-NJK-1

USM Number: 12204-510

Crane Pomerantz and Liborius Agwara
Defendant's Attorney

THE DEFENDANT:

☑ pleaded guilty to count(s) 1 of the Information ECF No. 106

☐ pleaded nolo contendere to count(s) which was accepted by the court.

☐ was found guilty on count(s) after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 U.S.C. § 641	Conversion of Government Property	9/1/2018	1

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s)

☑ Count(s) all remaining ☐ is ☑ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

5/5/2025
Date of Imposition of Judgment

Signature of Judge

Cristina D. Silva, United States District Judge
Name and Title of Judge

5/5/2025
Date

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

PROBATION

You are hereby sentenced to probation for a term of:

3 Years.

MANDATORY CONDITIONS

1. You must not commit another federal, state or local crime.
2. You must not unlawfully possess a controlled substance.
3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of placement on probation and at least two periodic drug tests thereafter, as determined by the court.
   - ☑ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(check if applicable)*
4. ☐ You must cooperate in the collection of DNA as directed by the probation officer. *(check if applicable)*
5. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. § 20901, *et seq*.) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(check if applicable)*
6. ☐ You must participate in an approved program for domestic violence. *(check if applicable)*
7. ☑ You must make restitution in accordance with 18 U.S.C. §§ 2248, 2259, 2264, 2327, 3663, 3663A, and 3664. *(check if applicable)*
8. You must pay the assessment imposed in accordance with 18 U.S.C. § 3013.
9. If this judgment imposes a fine, you must pay in accordance with the Schedule of Payments sheet of this judgment.
10. You must notify the court of any material change in your economic circumstances that might affect your ability to pay restitution, fines, or special assessments.

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

STANDARD CONDITIONS OF SUPERVISION

As part of your probation, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of the time you were sentenced, unless the probation officer instructs you to report to a different probation office or within a different time frame.
2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.
3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.
4. You must answer truthfully the questions asked by your probation officer.
5. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.
7. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
8. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.
9. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.
10. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchakus or tasers).
11. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting the permission of the court.
12. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the risk.
13. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's Signature _____ Date _____

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

SPECIAL CONDITIONS OF SUPERVISION

1. Access to Financial Information – You must provide the probation officer access to any requested financial information and authorize the release of any financial information. The probation office will share financial information with the U.S. Attorney's Office.

2. Financial Penalty – If the judgment imposes a financial penalty, you must pay the financial penalty in accordance with the Schedule of Payments sheet of this judgment. You must also notify the court of any changes in economic circumstances that might affect the ability to pay this financial penalty.

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Restitution	Fine	AVAA Assessment*	JVTA Assessment**
TOTALS	$ 25.00	$ 6,519.69	$ WAIVED	$	$

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss***	Restitution Ordered	Priority or Percentage
See attached Restitution List.		$6,519.69	

TOTALS	$ 0.00	$ 6,519.69

☐ Restitution amount ordered pursuant to plea agreement $ _____

☑ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Amy, Vicky, and Andy Child Pornography Victim Assistance Act of 2018, Pub. L. No. 115-299.
** Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.
*** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: FESTUS ONYEMALIOSIA EBONKA
CASE NUMBER: 2:22-cr-00156-CDS-NJK-1

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A ☑ Lump sum payment of $ 25.00 due immediately, balance due

☐ not later than _____, or
☑ in accordance with ☐ C, ☐ D, ☐ E, or ☑ F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☑ Special instructions regarding the payment of criminal monetary penalties:
Any unpaid balance shall be paid at a monthly rate of not less than 10% of any income earned and/or gross income while on probation, subject to adjustment by the Court based upon ability to pay.

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Case Number Defendant and Co-Defendant Names *(including defendant number)*	Total Amount	Joint and Several Amount	Corresponding Payee, if appropriate

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

☐ The defendant shall forfeit the defendant's interest in the following property to the United States:

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) AVAA assessment, (5) fine principal, (6) fine interest, (7) community restitution, (8) JVTA assessment, (9) penalties, and (10) costs, including cost of prosecution and court costs.

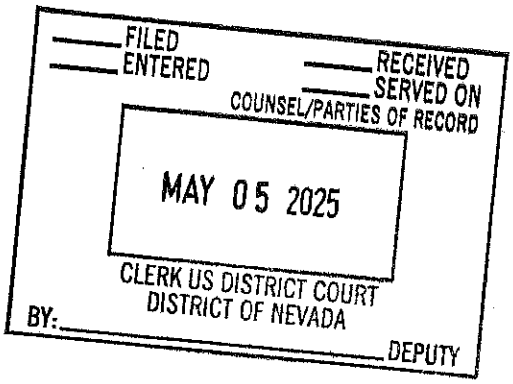
United States v. Festus Onyemaliosia Ebonka
2:22-cr-00156-CDS-NJK
Restitution List

Victim:

U.S. Dept of Health & Human Services
Centers of Medicare and Medicaid Services
7500 Security Boulevard
Mailstop C3-11-03
Baltimore MD 21244

Amount:

$6,519.69



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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, September 4, 2024. Brett Kandt, Esq., prosecuted the case before the Board. Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, was represented by counsel, Libo Agwara, Esq. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. The Board has jurisdiction over this matter and this Respondent because, at the time of the events herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

2. Respondent pre-signed two (2) controlled substance prescriptions that were issued to patients by his staff - on February 28, 2017, for patient J.J., and on March 2, 2017, for patient D.R. - while he was engaged in overseas travel outside of the United States from February 25 to March 11, 2017.

3. Board staff incurred at least $4,268.097 in attorney's fees and recoverable costs investigating and prosecuting this administrative action. The attorney's fees are reasonable based upon legal counsel's professional qualities, the nature of this administrative enforcement action, the work performed, and the result as evidenced by this Order.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and Respondent because, at the time of the events herein, Respondent held a controlled substance registration issued by the Board.

2. The applicable law in this matter is as follows:

A. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2353.

B. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

C. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

D. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

E. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or

revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

F. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

G. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

H. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

3. Respondent is GUILTY on Count One of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

4. Respondent is GUILTY on Count Two of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2353, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

5. Respondent is NOT GUILTY on Count Three of the Accusation.

6. Respondent is GUILTY on Count Four of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

7. Respondent is GUILTY on Count Five of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

8. Respondent is GUILTY on Count Six of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The certificate of registration of Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, is revoked pursuant to NRS 453.241(1)(b). The revocation is stayed, and Respondent is placed on probation for a period of three (3) years pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Pursuant to NRS 622.400, Respondent shall pay Four Thousand Two Hundred Sixty-Eight Dollars and Ninety-Seven Cents ($4,268.97) to partially reimburse the Board

for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by due and payable by September 4, 2025;

B. Respondent shall complete two (2) hours of training from Board staff on Nevada Prescription Monitoring Program (PMP) compliance by September 4, 2025;

C. Respondent shall complete two (2) hours of continuing education (CE) on ethics by September 4, 2025; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS23430 will be fully restored.

2. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately revoke Respondent's Certificate of Registration No. CS23430, and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

3. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5), and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

4. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 4th day of September, 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent pre-signed controlled substance prescriptions that were issued to patients by his staff while he was engaged in overseas travel. Respondent traveled outside of the United States on the following dates: July 14, 2016 – July 25, 2016; February 25, 2017 – March 11, 2017; September 27, 2017 – October 2, 2017; December 22, 2017 – December 28, 2017; and November 9, 2018 – November 30, 2018. Prescriber records and prescriptions document one-hundred and twenty-six (126) controlled substance prescriptions authorized by Respondent during these periods.

3. Respondent caused other practitioners who treated his patients to use his National Provider Identifier (NPI) while he was outside of the country to falsely bill Medicaid and other

commercial health insurance plans for services that Respondent did not personally provide, and received reimbursement for those services.

APPLICABLE LAW

4. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2355.

5. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

6. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

7. Medicaid fraud is a felony offense. 18 U.S.C. § 1347; 42 U.S.C.A. § 1320a-7b; NRS 422.540(1).

8. Insurance fraud is a felony offense. NRS 686A.2815; NRS 686A.291.

9. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act – Issuing Fraudulent Controlled Substance Prescriptions

14. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Issuing Fraudulent Controlled Substance Prescriptions

15. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS

453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2355, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Violations of Federal and State Law – Medicaid Fraud/Insurance Fraud

16. By falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1347, 42 U.S.C.A. § 1320a-7b, NRS 422.540(1), NRS 686A.2815 and/or NRS 686A.291, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

COUNT FOUR

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

17. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

18. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3

herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT SIX

Commission of Acts that Render Registration Inconsistent with the Public Interest

19. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

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DISTRICT COURT OF

CLARK COUNTY, NEVADA

FESTUS EBONKA, APRN, Petitioner, vs. NEVADA STATE BOARD OF PHARMACY, Respondent.	Case No. A-24-902608-J Dept. No. 29

ORDER DENYING PETITION FOR JUDICIAL REVIEW

This matter having come before this court on September 11, 2025, on Petitioner's Petition for Judicial Review; Liborius Agwara, Esq., appearing on behalf of Petitioner Festus Ebonka, APRN ("Ebonka") and Brett Kandt, Esq. appearing on behalf of the Respondent Nevada State Board of Pharmacy ("Board"); the Court having reviewed the papers and pleadings on file herein, having heard the arguments of counsel, and with good cause appearing, the Court hereby finds, concludes, and orders as follows:

Case Number: A-24-902608-J

FINDINGS OF FACT

The Notice of Intended Action and Accusation together with the Statement to Respondent and Notice of Hearing was filed and served on Ebonka on or about January 25, 2024, and originally noticed for a hearing on March 6, 2024. AR[1] 0001-0009. Ebonka filed an Answer and Notice of Defense on or about February 21, 2024. AR 0010-0011.

The Board held an evidentiary hearing on September 4, 2024. *See* Reporter's Transcript on file herein, AR 0377-0518. As stipulated by the parties, the entire case file was admitted into evidence. AR 0012-0369; AR 0381:20-0383:5. Based on the evidence presented, the Board after extensive deliberation made findings of fact, conclusions of law, and entered an order on September 4, 2024, imposing discipline on Ebonka, including a stayed revocation of his controlled substance registration, Certificate of Registration No. CS23430 (Order). AR 0370-0376; AR 0483:18-0517:14.

CONCLUSIONS OF LAW

The standard for judicial review is set forth in NRS 223B.135(3):

> The court shall not substitute its judgment for that of the agency as to the weight of evidence on a question of fact. The court may remand or affirm the final decision or set it aside in whole or in part if substantial rights of the petitioner have been prejudiced because the final decision of the agency is:
>
> (a) In violation of constitutional or statutory provisions;
> (b) In excess of the statutory authority of the agency;
> (c) Made upon unlawful procedure;
> (d) Affected by other error of law;
> (e) Clearly erroneous in view of the reliable, probative and substantial evidence on the whole record; or
> (f) Arbitrary or capricious or characterized by abuse of discretion.

See Nassiri v. Chiropractic Physicians' Bd., 130 Nev. 245, 249, 327 P.3d 487, 490 (2014).

---

[1] "AR" refers to the Administrative Record on file herein.

Ebonka only addresses questions of fact in the Memorandum of Points and Authorities in Support of Petition for Judicial Review. Specifically, Ebonka only focused on one issue for the Petition:

> 1. The Board's finding that Petitioner pre-signed two prescription scripts prior to his overseas trips was clearly erroneous in light of the reliable, probative and substantial evidence on the whole record, and therefore, was arbitrary, capricious and constitute[s] an abuse of discretion.

(Pet. at 5:15-20.)

This is fact specific. And as stated above, the Nevada Supreme Court, and the relevant statute are clear:

> The court shall not substitute its judgment for that of the agency as to the weight of evidence on a question of fact.

See Nassiri, 130 Nev. at 249, 327 P.3d at 490 (quoting 223B.135).

The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a).

There was substantial evidence elicited which supports the Board's finding that Ebonka pre-signed controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, in violation of 21 CFR § 1306.05(a).

The Board's determination was based on uncontroverted direct evidence in the form of the two written prescriptions together with Ebonka's own admissions, which conclusively established that the prescriptions were issued under his name and DEA registration number, on prescriptions pads from his office, while he was out of the country, to patients for whom he had previously prescribed the same schedule II controlled substances.

The only claims Ebonka made in his defense were that he did not sign the prescriptions, would never pre-sign a controlled substance prescription, and that they must be forgeries. The Board did not find Ebonka's alibi credible, and upon comparing the four samples of his signature on his written responses to the Board investigation with the signatures on the prescriptions, reasonably concluded that the signatures were in fact his.

This Court cannot overturn the Board's decision solely based upon Ebonka's dispute of the Board's findings. The Board had two versions of a story before it and did not believe Ebonka's version. This Court cannot overturn the Board's decision on this basis.

Ebonka raises several arguments for the first time in reply. This is inappropriate. Arguments may not be raised for the first time in a reply brief. *See Weaver v. State, Dep't of Motor Vehicles*, 121 Nev. 494, 502, 117 P.3d 193, 198-99 (2005) (arguments raised for the first time in an appellant's reply brief need not be considered); *see also Francis v. Wynn Las Vegas, LLC*, 127 Nev. 657, 671 n.7, 262 P.3d 705, 715 n.7 (2011) (same); *see also Khoury v. Seastrand*, 132 Nev. 520, 530 n.2, 377 P.3d 81, 88 n.2 (2016) (citing NRAP 28(c) and concluding that an issue raised for the first time in a reply brief was waived); *Hung v. Berhad*, 138 Nev. 547, 550 n.2, 513 P.3d 1285, 1288 n.2 (Nev. App. 2022) (the general rule [is] that arguments raised for the first time in [a] reply brief are deemed waived). As the factual arguments were the only focus of the opening brief that is all that is considered by the Court. The remaining arguments on other issues are waived.

ORDER

The Petition for Judicial Review is DENIED.

The Judgment of the Board is AFFIRMED.

IT IS SO ORDERED ~~this ___ day of _____, 2025.~~

Dated this 19th day of September, 2025

Jacob A. Reynolds

HONORABLE JACOB A. REYNOLDS

19F 9E6 BA98 0C4B
Jacob A. Reynolds
District Court Judge

Respectfully submitted by:

/s/ Brett Kandt

Brett Kandt, Esq. (Bar No. 5384)
General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy – Ste. 206
Reno NV 89521
Attorney for Respondent

Approved as to form and content by:

Liborius Agwara, Esq. (Bar No. 7576)
Law Office of Libo Agwara, Ltd.
2785 E. Desert Inn Road - Ste. 270
Las Vegas, NV 89121
Attorney for Petitioner

CSERV

DISTRICT COURT
CLARK COUNTY, NEVADA

Festus Ebonka, APRN, Petitioner(s) vs. Nevada State Board of Pharmacy, Respondent(s)	CASE NO: A-24-902608-J DEPT. NO. Department 29

AUTOMATED CERTIFICATE OF SERVICE

This automated certificate of service was generated by the Eighth Judicial District Court. The foregoing Order was served via the court's electronic eFile system to all recipients registered for e-Service on the above entitled case as listed below:

Service Date: 9/19/2025

Law Office	agwaralaw@yahoo.com
Liborius Agwara	libolaw@yahoo.com
Liborius Agwara	libolaw@yahoo.com
WM Kandt	bkandt@pharmacy.nv.gov

STATE OF NEVADA

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

CATHY DINAUER
Executive Director

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS

NEVADA STATE BOARD OF NURSING

October 8, 2025

Nevada State Board of Pharmacy
Attn: Brett Kandt
bkandt@pharmacy.nv.gov

Re: Public record request, Festus Ebonka

To whom it may concern:

Please be advised that we have received your public records request. We have reviewed our records. We have attached the documents responsive to your public record request.

If you have any questions, please do not hesitate to contact my office.

Sincerely,

Kimberly Arguello
General Counsel
702-668-4534
karguello@nsbn.state.nv.us
Enclosures

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF FESTUS EBONKA ADVANCED PRACTICE REGISTERED NURSE NEVADA LICENSE NO. APRN000902 RESPONDENT	COMPLAINT AND NOTICE OF HEARING CASE NO. 2024100049

The Nevada State Board of Nursing (Board), by and through counsel, Kimberly A. Arguello, hereby notifies Respondent FESTUS EBONKA (Respondent) of an administrative hearing, which is to be held pursuant to Chapters 233B and 632 of the Nevada Revised Statutes and Chapter 632 of the Nevada Administrative Code. The purpose of the hearing is to consider the allegations stated below and to determine if the Respondent should be subject to an administrative penalty as set forth in NRS 632.347 and/or NRS 632.325 and/or NAC 632.926-.927, if the stated allegations are proven at the hearing by the evidence presented.

Respondent was at the time of the allegations stated below, licensed as an Advanced Practice Registered Nurse in the State of Nevada, and is, therefore, subject to the jurisdiction of the Board and the provisions of NRS Chapter 632 and NAC Chapter 632.

IT IS HEREBY ALLEGED AND CHARGED AS FOLLOWS:

I.

On or about June 15, 2006, Respondent was granted a permanent Advanced Practice Registered Nurse's license (APRN) in the State of Nevada.

On or about May 5, 2025, before the United States District Court, District of Nevada, Respondent, after a plea of guilty, was adjudicated guilty of one count of Conversion of Government Property, a violation of 18 U.S.C. Section 641.

II.

The foregoing conduct constitutes grounds for disciplinary action pursuant to NRS 632.347(1)(b) unprofessional conduct, because Respondent is guilty of any offense (2) related to the qualifications, functions or duties of a licensee or holder of a certificate, in which case the record of conviction is conclusive evidence thereof.

Based on the foregoing:

PLEASE TAKE NOTICE, that a disciplinary hearing has been set to consider this Administrative Complaint against the above-named Respondent in accordance with Chapters 233B and 632 of the Nevada Revised Statutes and Chapter 632 of the Nevada Administrative Code.

THE HEARING WILL TAKE PLACE on **Thursday, September 18, 2025, commencing at 09:00 a.m.,** or as soon thereafter as the Board is able to hear the matter, at the **Office of the Nevada State Board of Nursing, 6005 Plumas Street, Room 101, Reno, NV 89519.** This case and other matters are scheduled to be heard by the Board.

This Nevada State Board of Nursing meeting will also be held virtually via Microsoft Teams. The link to the Teams meeting is:

To join by VIDEO/TELECONFERENCE

https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZjY3MDc5MTUtODRmNi00NWI2LWJlNjMtN2YwMTBhZTZhMDU5%40thread.v2/0?context=%7b%22Tid%22%3a%22e4a340e6-b89e-4e68-8eaa-1544d2703980%22%2c%22Oid%22%3a%2243df6cf6-38b0-4aad-b524-d5e9ab50ece4%22%7d

To join by meeting ID through Microsoft Teams:

Meeting ID: 283 625 547 899 7

Passcode: Tj6Dj9Tf

To join by telephone:

Audio Conference Number: +1 775-321-6111

Phone Conference ID: 704 745 453#

This case and other matters are scheduled to be heard by the Board.

PURSUANT TO NRS 632.350, Respondent may request, in writing, that the Board furnish copies of communications, reports, and affidavits in its possession, regarding the above-referenced matter.

As the Respondent, you are specifically informed that you have the right to appear, either in person at the physical address listed above, or virtually, at the log-in address listed above, and be heard in your defense, either personally or through counsel of your choice. You have the right to respond and to present relevant evidence and argument on all issues involved. You have the right to call and examine witnesses, introduce exhibits, and cross-examine opposing witnesses on any matter relevant to the issues involved.

You have the right to request that the Board issue subpoenas to compel witnesses to testify and/or evidence to be offered on your behalf. In making this request, you may be required to demonstrate the relevancy of the witness' testimony and/or evidence.

The purpose of the hearing is to determine if the Respondent has violated NRS 632.347(1)(b), and if the allegations contained herein are substantially proven by the evidence presented to further determine what administrative penalty is to be assessed against the Respondent, if any, pursuant to NRS 632.347 and/or NRS 632.325 and/or NAC 632.926-.927.

Should the Respondent fail to appear at the hearing, a decision may still be reached by the Board. As the Respondent, you are further advised that you may be charged with cost associated with the hearing pursuant to NRS 622.400.

Pursuant to NRS 233B.121(5), informal disposition of this case may be made by stipulation, agreed settlement, consent order, or default. Any attempt to negotiate this case

should be made through Kimberly A. Arguello, General Counsel, Nevada State Board of Nursing.

Pursuant to NRS 241.033(2)(b), the Nevada State Board of Nursing may, without further notice, take administrative action against your license and/or certificate to practice within the State of Nevada if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health.

DATED this 7th day of August 2025.

By: _____

KIMBERLY A. ARGUELLO, ESQ.
General Counsel
Nevada State Board of Nursing
4220 S. Maryland Parkway, Suite B300
Las Vegas, Nevada 89119
(702) 668-4534

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Nursing, and that on this 22nd day of August 2025, I served a copy of the foregoing COMPLAINT AND NOTICE OF HEARING, by placing said document in the U.S. Mail by first class mail and by the U.S. Mail, certified, return receipt requested and postage prepaid, addressed to:

Festus Ebonka
[redacted]

By Email to: [redacted]

Corina Jimenez
Executive Assistant
Nevada State Board of Nursing

ORIGINAL

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF FESTUS EBONKA ADVANCED PRACTICE REGISTERED NURSE NEVADA LICENSE NO. APRN000902 RESPONDENT	FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER. CASE NO. 2024100049

On Thursday, September 18, 2025, a hearing was held in the above matter before the Nevada State Board of Nursing ("Board") in compliance with the provisions of Chapters 233B and 632 of the Nevada Revised Statutes (NRS) and Chapter 632 of the Nevada Administrative Code (NAC).

Respondent FE TUS EBONKA appeared at the hearing in proper person. The Nevada State Board of Nursing appeared through counsel, Kimberly A. Arguello, Esq.

At the hearing, documents were admitted into evidence and sworn testimony was provided. The Board made the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

The Board, based upon evidence presented during the Hearing, finds that there is a preponderance of evidence in the record to establish each of the following findings of fact:

1. At least twenty-one (21) working days prior to the date of the hearing, Respondent had been noticed of the hearing by certified mail and by first class mail, which notice was mailed to Respondent's last known residential address.

2. The Board had jurisdiction over the matter, and the Board could proceed to make a determination in the matter.

3. On June 15, 2006, Respondent was granted a permanent Advanced Practice Registered Nurse's license (APRN) in the State of Nevada.

4. On May 5, 2025, before the United States District Court, District of Nevada, Respondent, after a plea of guilty, was adjudicated guilty of one count of Conversion of Government Property, a violation of 18 U.S.C. Section 641.

CONCLUSIONS OF LAW

Based upon the above Findings of Fact, the Board hereby finds by a preponderance of the evidence the following violation of law:

Respondent is in violation of NRS 632.347(1)(b) unprofessional conduct, because Respondent is guilty of any offense (2) related to the qualifications, functions or duties of a licensee or holder of a certificate, in which case the record of conviction is conclusive evidence thereof.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law and good cause appearing, therefore,

IT IS ORDERED that Respondent EBONKA's Nevada APRN license No. APRN000902 is Suspended. The suspension of Respondent's Nevada APRN license No. APRN000902 shall be for a term of 6 months. Additionally, Respondent shall provide proof to Board staff of the completion of a 30 hour Continuing Education course on Ethics within 6 months.

This Order shall become part of Respondent's permanent record, be published on the Board's list of disciplinary actions, and be reported to the appropriate data banks.

This Order shall become effective on 9th of November 2025.

DATED this 6th day of October 2025.

NEVADA STATE BOARD OF NURSING

By: _____

CHERYL A. MAES, Ph.D., APRN, FNP-BC
Board President

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Nursing, and that on this 6th day of October 2025, I served a copy of the foregoing FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER, by placing said document in the U.S. Mail by first class mail and by the U.S. Mail, certified, return receipt requested and postage prepaid, addressed to:

Festus Ebonka
[redacted]

By Email to: [redacted]

Corina Jimenez
Executive Assistant
Nevada State Board of Nursing

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

October 9, 2025

VIA U.S. CERTIFIED MAIL AND ELECTRONIC MAIL TO: libolaw@yahoo.com & agwa-ralaw@yahoo.com

Festus Ebonka, APRN
c/o Liborius Agwara, Esq.
2785 E. Desert Inn Road, Ste. 270
Las Vegas, NV 89121

Re: Notice of Suspension of Registration No. CS23430 (Case Nos. 19-012-CS-S/25-215-CS-S)

Dear Mr. Ebonka:

The Nevada State Board of Pharmacy (Board) has been notified that the Nevada State Board of Nursing (NSBN) entered an order on October 6, 2025, suspending your License No. APRN000902 for 6 months effective November 9, 2025. Pursuant to NRS 639.2107, when the suspension of your License No. APRN000902 takes effect on November 9, 2025, this will operate as an immediate suspension of your Certificate of Registration No. CS23430 with the Board.

Once the suspension of your Certificate of Registration No. CS23430 takes effect you may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense any controlled substance or dangerous drug until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your registration. Your PMP account will also suspended pursuant to NAC 453.078. You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

This will also confirm that through your counsel you are stipulating to a continuance of the hearing noticed for October 15, 2025, in Case No. 25-215-CS-S, during your suspension period; the hearing will be re-noticed for March 4, 2026. Please be advised that the district court entered an order in Case No. A-24-902608-J denying your petition for judicial review and affirming the Board's order entered September 4, 2024, in Case No. 19-012-CS-S; any failure to comply with that order will result in the issuance of an order to show cause pursuant to NAC 639.965.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

5H

FILED
JAN 0 7 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN CHRISTOPHER CLEMENTS, RPH, Certificate of Registration No. 21841,** **and,** **CVS PHARMACY #8822, Pharmacy License No. PH01145,** **Respondents.**	**Case Nos. 23-051-RPH-S** **23-051-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Ryan Christopher Clements ("Respondent Clements"), because Respondent Clements holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing him to engage in the practice of pharmacy in the state of Nevada.

2. The Board has jurisdiction over Respondent CVS Pharmacy #8822 ("Respondent CVS"), because Respondent CVS holds a license issued by the Board pursuant to NRS 639.230, authorizing the operation of a pharmacy located at 2594 Wigwam Parkway, in Henderson, Nevada.

FACTUAL ALLEGATIONS

3. In January 2023, Respondent Clements, the holder of pharmacist registration no. 21841, was employed by Respondent CVS at its pharmacy on Wigwam Parkway, in Henderson, Nevada.

4. On January 16, 2023, while on duty at the CVS Pharmacy on Wigwam Parkway, Respondent Clements refilled a prescription for patient S.D., who had been taking Losartan 100 mg tablets for her hypertension.

5. For identification purposes, the CVS Pharmacy prescription management system assigned no. 1620739 to the above prescription.

6. Before dispensing the medication to patient S.D., Respondent Clements erroneously filled the amber vial with 50 mg tablets instead of 100 mg tablets as specified on the prescription.

7. Respondent Clements dispensed patient S.D.'s medication in an amber vial labeled as containing 100 mg tablets even though it contained 50 mg tablets.

8. Patient S.D. ingested approximately 5 doses of her medication, believing that she had received 100 mg tablets as indicated on the amber vial.

9. Despite taking her medication as directed, patient S.D. reportedly experienced dizziness, a flushed face, and an erratic heartbeat.

10. Given the above symptoms of hypertension, patient S.D. closely examined her tablets to make sure that she had received the correct medication. When she did so, she discovered that the manufacturer's imprint code on the tablets corresponded to the Losartan 50 mg tablet and not the 100mg tablet.

11. Patient S.D. returned the tablets to the pharmacy, where she spoke with Pharmacist Daniel Chasin.

12. Pharmacist Chasin examined the tablets for patient S.D, verified that her prescription for 100 mg tablets had been incorrectly refilled with 50 mg tablets, and then he telephoned patient S.D.'s provider to report the error.

13. Patient S.D.'s blood pressure was significantly elevated during the time that she was taking 50 mg tablets.

14. Despite having used accuracy scan technology, Respondent Clements was unable to explain why the label on patient S.D.'s prescription did not correctly identify the strength of the tablets that were dispensed to her.

15. Respondent Clements admittedly filled patient's S.D.'s prescription with 50 mg tablets instead of 100 mg tablets and then failed to identify his mistake when he performed the final product verification.

APPLICABLE LAW

16. The Board may discipline any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

17. A pharmacist's conduct is unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling, or if the pharmacist performs his duties in a negligent manner. NAC 639.945(1)(d) and (i).

18. A dispensing pharmacist is responsible for verifying the selection and strength of the drug dispensed, and the correct labeling of the container in which it is dispensed. NAC 639.252.

19. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers, and/or pharmacists are responsible for the acts and omissions of the pharmacy workers under their supervision and/or in their employ.

COUNT ONE
Unprofessional Conduct by a Pharmacist

20. On January 16, 2023, while on duty at the CVS Pharmacy on Wigwam Parkway in Henderson, Nevada, Respondent Clements incorrectly filled patient S.D.'s prescription for Losartan with 50 mg tablets instead of 100 mg tablets.

21. Respondent Clements had a duty to verify the selection and strength of the drug that he dispensed to patient S.D., and the correct labeling of the amber vial in which he dispensed it.

22. Respondent Clements breached the above duty.

23. Respondent Clements' conduct as alleged above was unprofessional because he failed to strictly follow the instructions of patient S.D.'s provider regarding the strength of the tablets to be dispensed to her.

24. Respondent Clements' conduct as alleged above was unprofessional because he performed his duties as a pharmacist in a negligent manner.

25. Respondent Clements unprofessional conduct caused patient S.D. to experience elevated blood pressure.

26. Respondent Clements may be disciplined by the Board for the unprofessional conduct as described above.

COUNT TWO
Pharmacy Liability

27. As the owner/operator of the pharmacy at which Respondent Clements worked, Respondent CVS is responsible for Respondent Clements' unprofessional conduct as described above.

28. Respondent CVS may be disciplined by the Board for Respondent Clements' unprofessional conduct as described above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondents Clements and the pharmacy license of Respondent CVS.

DATED this 7th day of January, 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8822,** **Pharmacy License No. PH01145,** **Respondent.**	**Case No. 23-051-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8822,** **Pharmacy License No. PH01145,** **Respondent.**	**Case No. 23-051-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #8822

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of January 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

CVS Pharmacy #8822
2594 Wigwam Pkwy.
Henderson, NV 89074

Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

And via courtesy EMAIL: brian.convery@cvshealth.com

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN CHRISTOPHER CLEMENTS, RPH, Certificate of Registration No. 21841,** **and,** **CVS PHARMACY #8822, Pharmacy License No. PH01145,** **Respondents.**	**Case No. 23-051-RPH-S** **23-051-PH-S** **STIPULATION AND ORDER (Respondent CVS Pharmacy Only)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent CVS Pharmacy #8822 ("Respondent CVS"), by and through its undersigned representative, hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent CVS.

2. The Board's staff properly served Respondent CVS with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent CVS understands the terms of this Stipulation, and its undersigned representative has executed it knowingly and voluntarily.

4. Respondent CVS is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent CVS under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, and NRS Chapter 639, the Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent CVS has failed to comply with the provisions of the

paragraphs below, Respondent CVS voluntarily waives the right to have a hearing before the Board, to petition for reconsideration of any adverse decision by the Board, to petition for judicial review of such an adverse decision, and other rights related to this action as identified above.

6. Respondent CVS does not contest the charge against it and admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the alleged violations, to wit:

A. On January 16, 2023, while on duty at the CVS Pharmacy #8822 on Wigwam Parkway in Henderson, Nevada, Ryan Christopher Clements, a CVS employee, refilled a prescription for patient S.D., who had been taking Losartan 100 mg tablets for her hypertension.

B. Clements mistakenly refilled patient's S.D.'s prescription with 50 mg tablets instead of 100 mg tablets, as prescribed, and then he failed to identify his mistake when he performed the final product verification.

C. Patient S.D. reported that she took the 50 mg tablets dispensed to her, instead of the 100 mg tablets as prescribed, for approximately 10 days before she noticed the above mistake.

D. Patient S.D. reported that she experienced symptoms of hypertension during the time when she took the 50 mg tablets.

E. Respondent CVS accepts responsibility for the conduct of Ryan Christopher Clements as described above.

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent CVS agree to the imposition of the following penalties:

A. Respondent CVS shall pay an administrative fine of One Thousand and 00/100 Dollars ($1000.00) for the violation alleged in Count Two of the Accusation. Respondent CVS shall pay this sum by *business check, certified check* or *money order* payable to "**State of Nevada, Office of the Treasurer.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by April 30, 2026.

B. Respondent CVS shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred investigating and prosecuting this matter. Respondent CVS shall pay this sum by *certified check* or *money order* payable to **"Nevada State Board of Pharmacy."** Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by April 30, 2026.

8. Failure by Respondent CVS to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent CVS to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation, the Board may impose additional discipline consistent with the provisions of NRS Chapter 639.

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondent CVS fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

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Respondent CVS has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 02/04/2026 **day of January 2026.**

CVS PHARMACY #8822

By _____

Name: Leigh Parenteau
Title: Lead Director, Regulatory Affairs

Signed this 4th **day of** February **2026.**

NEVADA STATE BOARD OF PHARMACY

By _____

GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar 4805

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case Nos. 23-051-PH-S and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered March 4, 2026

_____
Helen Park, President
Nevada State Board of Pharmacy

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

RYAN CHRISTOPHER CLEMENTS, RPH, Certificate of Registration No. 21841,

and,

CVS PHARMACY #8822, Pharmacy License No. PH01145,

Respondents.

Case Nos. 23-051-RPH-S
23-051-PH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Ryan Christopher Clements ("Respondent Clements"), because Respondent Clements holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing him to engage in the practice of pharmacy in the state of Nevada.

2. The Board has jurisdiction over Respondent CVS Pharmacy #8822 ("Respondent CVS"), because Respondent CVS holds a license issued by the Board pursuant to NRS 639.230, authorizing the operation of a pharmacy located at 2594 Wigwam Parkway, in Henderson, Nevada.

FACTUAL ALLEGATIONS

3. In January 2023, Respondent Clements, the holder of pharmacist registration no. 21841, was employed by Respondent CVS at its pharmacy on Wigwam Parkway, in Henderson, Nevada.

4. On January 16, 2023, while on duty at the CVS Pharmacy on Wigwam Parkway, Respondent Clements refilled a prescription for patient S.D., who had been taking Losartan 100 mg tablets for her hypertension.

5. For identification purposes, the CVS Pharmacy prescription management system assigned no. 1620739 to the above prescription.

6. Before dispensing the medication to patient S.D., Respondent Clements erroneously filled the amber vial with 50 mg tablets instead of 100 mg tablets as specified on the prescription.

7. Respondent Clements dispensed patient S.D.'s medication in an amber vial labeled as containing 100 mg tablets even though it contained 50 mg tablets.

8. Patient S.D. ingested approximately 5 doses of her medication, believing that she had received 100 mg tablets as indicated on the amber vial.

9. Despite taking her medication as directed, patient S.D. reportedly experienced dizziness, a flushed face, and an erratic heartbeat.

10. Given the above symptoms of hypertension, patient S.D. closely examined her tablets to make sure that she had received the correct medication. When she did so, she discovered that the manufacturer's imprint code on the tablets corresponded to the Losartan 50 mg tablet and not the 100mg tablet.

11. Patient S.D. returned the tablets to the pharmacy, where she spoke with Pharmacist Daniel Chasin.

12. Pharmacist Chasin examined the tablets for patient S.D, verified that her prescription for 100 mg tablets had been incorrectly refilled with 50 mg tablets, and then he telephoned patient S.D.'s provider to report the error.

13. Patient S.D.'s blood pressure was significantly elevated during the time that she was taking 50 mg tablets.

14. Despite having used accuracy scan technology, Respondent Clements was unable to explain why the label on patient S.D.'s prescription did not correctly identify the strength of the tablets that were dispensed to her.

15. Respondent Clements admittedly filled patient's S.D.'s prescription with 50 mg tablets instead of 100 mg tablets and then failed to identify his mistake when he performed the final product verification.

APPLICABLE LAW

16. The Board may discipline any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

17. A pharmacist's conduct is unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling, or if the pharmacist performs his duties in a negligent manner. NAC 639.945(1)(d) and (i).

18. A dispensing pharmacist is responsible for verifying the selection and strength of the drug dispensed, and the correct labeling of the container in which it is dispensed. NAC 639.252.

19. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers, and/or pharmacists are responsible for the acts and omissions of the pharmacy workers under their supervision and/or in their employ.

COUNT ONE
Unprofessional Conduct by a Pharmacist

20. On January 16, 2023, while on duty at the CVS Pharmacy on Wigwam Parkway in Henderson, Nevada, Respondent Clements incorrectly filled patient S.D.'s prescription for Losartan with 50 mg tablets instead of 100 mg tablets.

21. Respondent Clements had a duty to verify the selection and strength of the drug that he dispensed to patient S.D., and the correct labeling of the amber vial in which he dispensed it.

22. Respondent Clements breached the above duty.

23. Respondent Clements' conduct as alleged above was unprofessional because he failed to strictly follow the instructions of patient S.D.'s provider regarding the strength of the tablets to be dispensed to her.

24. Respondent Clements' conduct as alleged above was unprofessional because he performed his duties as a pharmacist in a negligent manner.

25. Respondent Clements unprofessional conduct caused patient S.D. to experience elevated blood pressure.

26. Respondent Clements may be disciplined by the Board for the unprofessional conduct as described above.

COUNT TWO
Pharmacy Liability

27. As the owner/operator of the pharmacy at which Respondent Clements worked, Respondent CVS is responsible for Respondent Clements' unprofessional conduct as described above.

28. Respondent CVS may be disciplined by the Board for Respondent Clements' unprofessional conduct as described above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondents Clements and the pharmacy license of Respondent CVS.

DATED this 7th day of January, 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN CHRISTOPHER CLEMENTS, RPH, Certificate of Registration No. 21841,** **Respondent.**	**Case No. 23-051-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN CHRISTOPHER CLEMENTS, RPH, Certificate of Registration No. 21841,** **Respondent.**	**Case No. 23-051-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

RYAN CHRISTOPHER CLEMENTS, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of January 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Ryan Clements, RPH
[redacted]
Elko, NV [redacted]

Ryan Clements, RPH
c/o CVS Pharmacy
550 W Idaho St.
Elko, NV 89801

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
JAN 2 6 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN CHRISTOPHER CLEMENTS, RPH, Certificate of Registration No. 21841,** **Respondent.**	**Case No. 23-051-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

From: ryancclements92
To: Brett Kandt
Cc: Board Coordination
Subject: Case Nos 23-051-RPH-S
Date: Friday, January 23, 2026 8:51:09 AM

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello,

My name is Ryan Clements and I am responding to a Notice of Intended Action and Accusation. It is case nos 23-051-RPH-S and 23-051-PH-S. It was filed January 7th 2026 about an event in January 2023. A hearing was scheduled in March 2026 for me to appeal this Accusation. However, I am not looking to do so. I worked with Ken, the inspector, at the time of this error and I do not contest the events listed in this Accusation.
I tried to call the Board and notify my acceptance of these events, but was requested to email you instead. I am not sure if this is satisfactory to fulfill the legal aspect of this Action, but I do waive my right to this Hearing and I do not wish to contest or appeal the Accusation of the Board. I accept what discipline the Board may issue. I did speak with the patient during this investigation years ago and made clear my error and my commitments to prevent such mistakes in the future.

You or anyone from the Board may contact me at this email or at my personal cell number, [redacted], for any additional information. I thank you for your time.

Ryan Clements.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN CHRISTOPHER CLEMENTS, RPH, Certificate of Registration No. 21841,** **and,** **CVS PHARMACY #8822, Pharmacy License No. PH01145,** **Respondents.**	**Case No. 23-051-RPH-S** **23-051-PH-S** **STIPULATION AND ORDER (Respondent Clements Only)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Ryan Christopher Clements ("Respondent"), hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent understands the terms of this Stipulation, and he has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, and NRS Chapter 639, the Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of the paragraphs below, Respondent voluntarily waives the right to have a hearing before the Board, to petition for reconsideration of any adverse decision by the Board, to petition for judicial review of such an adverse decision, and other rights related to this action as identified above.

6. Respondent does not contest the charge against him and admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the alleged violations, to wit:

A. On January 16, 2023, while on duty at the CVS Pharmacy #8822 on Wigwam Parkway in Henderson, Nevada, Respondent refilled a prescription for patient S.D., who had been taking Losartan 100 mg tablets for her hypertension.

B. Respondent mistakenly refilled patient's S.D.'s prescription with 50 mg tablets instead of 100 mg tablets, as prescribed, and then he failed to identify his mistake when he performed the final product verification.

C. Patient S.D. reported that she took the 50 mg tablets instead of the 100 mg tablets as prescribed for approximately 10 days before she noticed the mistake.

D. Patient S.D. reported that she experienced symptoms of hypertension during the time when she took the 50 mg tablets.

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of One Thousand and 00/100 Dollars ($1000.00) for the violations alleged in Count One of the Accusation. Respondent shall pay this sum by *certified check* or *money order* payable to **"State of Nevada, Office of**

the Treasurer." Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by April 30, 2026.

B. Respondent shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. Respondent shall pay this sum by *certified check* or *money order* payable to **"Nevada State Board of Pharmacy."** Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by April 30, 2026.

8. Failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in findings of a violation, the Board may impose additional discipline consistent with the provisions of NRS Chapter 639.

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms

and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

Respondent CVS has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein

AGREED:

Signed this 31st day of January 2026.

RYAN CHRISTOPHER CLEMENTS
Registration No. 21841

Signed this 31st day of January 2026.

NEVADA STATE BOARD OF PHARMACY

By_____
GREGORY L. ZUNINO
Senior General Counsel

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case Nos. 23-051-RPH-S and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered March 4, 2026

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5J

FILED
JUL 2 4 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondents.**	**Case Nos. 24-370-PH-N** **24-370-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (the "Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent PharMerica ("Respondent PharMerica"), the holder of Pharmacy License No. PH02018, because Respondent PharMerica is licensed by the Board to operate a pharmacy at 4750 Longley Lane in Reno, Nevada.

2. The Board has jurisdiction over Respondent Camilla Kim, RPh ("Respondent Kim"), the holder of Certificate of Registration No. 19388, because Respondent Kim is registered by the Board to engage in the practice of pharmacy in Nevada.

FACTUAL ALLEGATIONS

3. Respondent PharMerica operates a pharmacy in Reno, Nevada.

4. In March 2024, Respondent Kim was employed by Respondent PharMerica as a pharmacist.

5. In 2023 and 2024, Respondent PharMerica was under contract with MorningStar Senior Living of Sparks ("MorningStar"), an assisted living facility, to dispense prescription medication and provide medication management services to residents of the MorningStar facility.

6. Respondent PharMerica worked cooperatively with the nursing staff at MorningStar to store and deliver prescription medications for the residents of the MorningStar facility.

7. In 2023 and 2024, patient D.P., an 87-year-old female, resided at MorningStar, where she received medication and medication management services from Respondent PharMerica.

8. In 2023 and 2024, patient D.P. required levothyroxine for hypothyroidism.

9. Between March 2023 and March 2024, Respondent PharMerica dispensed levothyroxine to patient D.P. without interruption, according to the instructions of patient D.P.'s physician.

10. On March 6, 2024, patient D.P.'s physician issued her a new prescription for levothyroxine. The prescription directed Respondent PharMerica to dispense an initial 90-day supply of levothyroxine with two refills.

11. On its face, the above prescription sufficed to meet patient D.P.'s medical needs for 12 months.

12. Patient D.P.'s physician electronically transmitted the above prescription to Respondent PharMerica.

13. Respondent PharMerica assigned no. 343217 to the above prescription. Per standard operating procedure, PharMerica processed prescription no. 343217 at its facility in Kentucky.

14. At the facility in Kentucky, a pharmaceutical technician transferred the information from the electronic prescription to a computerized prescription management system.

15. When transferring the prescription information, the technician incorrectly entered code "X90D" related to the "duration" of medication treatment. This code suppressed the automatic refill

function on the system, thus instructing the system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

16. Since patient D.P.'s levothyroxine was considered a "maintenance" medication, there should not have been a duration code associated with prescription no 343217.

17. In March 2024, before dispensing any medication under prescription no. 343217, Respondent Kim verified the prescription at PharMerica's facility in Reno.

18. When verifying the above prescription, Respondent Kim failed to notice that the duration code X90D, as described above, was inconsistent with the number of refill authorizations on the prescription itself. As noted above, this code instructed the automated system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

19. In June of 2024, due to Respondent Kim's omission as described above, PharMerica failed to refill patient D.P.'s prescription for levothyroxine as directed by her physician.

20. Between June and September 2024, the nursing staff at MorningStar delivered no levothyroxine to patient D.P., and they made no inquiries of PharMerica concerning the abrupt cessation of patient D.P.'s medication treatment.

21. In August or September 2024, patient D.P.'s daughter observed that her mother's health had rapidly declined for no apparent reason. She alerted the nursing staff at MorningStar and/or patient D.P.'s physician.

22. In September 2024, Patient D.P. was admitted to the intensive care unit at Renown Hospital, where she was diagnosed with myxedema coma and cellulitis in her left leg. These medical conditions were caused by the cessation of medication treatment with levothyroxine.

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APPLICABLE LAW

23. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Unprofessional conduct includes "failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling." NAC 639.945(1)(d).

25. Unprofessional conduct includes performing one's duties as the holder of a certificate of registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

26. A pharmacist has a duty to supervise a pharmaceutical technician who performs one or more of the functions necessary to prepare a prescription. NAC 639.252. This includes the duty to verify the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

27. A pharmacist has a duty to maintain a record of each refill of a prescription. NAC 639.918.

28. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

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COUNT ONE
Unprofessional Conduct by a Pharmacist
(Respondent Kim)

29. As alleged above, Respondent Kim verified prescription no. 343217 for levothyroxine, including two refills. In verifying the prescription, Respondent Kim failed to notice that a pharmaceutical technician in Kentucky had incorrectly entered a duration code into PharMerica's prescription management system, thus causing the system to suppress the automatic refill function.

30. Respondent Kim had a duty to supervise the pharmaceutical technician in Kentucky who performed data entry tasks related to prescription no. 343217.

31. Respondent Kim had a duty to correct the data entry error described above.

32. Respondent Kim had a duty to strictly follow the instructions of patient D.P.'s physician as to the refilling of no. 343217.

33. Respondent Kim performed the above duties in an incompetent, unskillful or negligent manner.

34. Due to Respondent Kim's unprofessional conduct as described above, patient D.P. suffered harm.

35. For her unprofessional conduct as described above Respondent Kim is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

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COUNT TWO

Employer Liability for Unprofessional Conduct
(Respondent PharMerica)

36. Respondent Kim engaged in unprofessional conduct as described above.

37. As Respondent Kim's employer at the time, Respondent PharMerica is responsible for the unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

38. For said unprofessional conduct, Respondent PharMerica is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Camilla Kim and the pharmacy license of Respondent PharMerica.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **Respondent.**	**Case No. 24-370-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **Respondent.**	**Case No. 24-370-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR PharMerica

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

PharMerica
4750 Longley Ln #204
Reno, NV 89502

Camilla Kim, RPh
[redacted]
Reno, NV [redacted]

PharMerica
c/o Camilla Kim, RPh
4750 Longley Ln #204
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
AUG 29 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH0218,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388.** **Respondents.**	**Case Nos. 24-370-PH- N** **24-370-RPH-N** **RESPONDENTS' ANSWER AND NOTICE OF DEFENSE**

Respondents PharMerica and Camilla Kim, RPH, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-2

Paragraph 1: Respondent PharMerica acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1.

Paragraph 2: Respondent Kim acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2.

Factual Allegations: Paragraphs 3-22

Paragraph 3: Respondent PharMerica acknowledges that it operates a pharmacy located in Reno, Nevada as set forth in Paragraph 3.

Paragraph 4: Respondent Kim acknowledges that she was employed by PharMerica in March 2024 as set forth in Paragraph 4.

Paragraph 5: Respondent PharMerica acknowledges that during the time periods set forth in Paragraph 5, it did dispense prescribed medication to residents of MorningStar Senior Living of Sparks as set forth in Paragraph 5.

Paragraph 6: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 6 to the extent the PharMerica coordinated deliveries of prescribed and dispensed medication to the nursing staff of MorningStar Senior Living.

Paragraph 7: Respondent PharMerica agrees that patient D.P. did receive some medication management services in the time frame noted in Paragraph 7.

Paragraph 8: Respondents are without sufficient personal knowledge to respond to the factual assertions contained in Paragraph 8.

Paragraph 9: Respondent PharMerica agrees with the factual assertions in Paragraph 9 to the extent that patient D.P. received levothyroxine in 2023 through the end of February 2024.

Paragraph 10: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 10 to the extent that a new prescription (no. 343217, the "Prescription") was issued March 6, 2024, by patient D.P.'s physician. However, the directions for the prescription were for one tablet daily for a 90-day duration with three refills, not two refills as noted in Paragraph 10 and further the prescription authorized three refills but did not direct automatic refills of the Prescription.

Paragraph 11: Respondents are without personal knowledge to substantively respond to the factual assertions set forth in Paragraph 11, however Respondents acknowledge that had the Prescription been refilled by patient D.P. as allowed, there would have been approximately twelve months of medication authorized by the physician.

Paragraph 12: Respondent PharMerica acknowledges that it received Prescription no. 343217 electronically.

Paragraph 13: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 13.

Paragraph 14: Based on information and belief, Respondent PharMerica agrees that a PharMerica pharmacy technician would have transcribed the Prescription information into PharMerica's computerized prescription management system.

Paragraph 15: Respondents deny that the pharmacy technician incorrectly entered code "X90D" into the prescription management system. The technician correctly entered the Prescription and directions into the prescription management system; because the Prescription directions included a duration, the prescription management system automatically assigned the code to the Prescription. The prescription management system did not terminate D.P.'s supply of levothyroxine at the end of the initial ninety days; the Prescription was still active and simply needed to be refilled by MorningStar Senior Living.

Paragraph 16: Respondents disagree with the factual assertions contained in Paragraph 16; prescriptions, including prescriptions for "maintenance" medications, often have a duration associated with them.

Paragraph 17: Respondent Kim acknowledges that she verified Prescription no. 343217 before the Prescription was initially dispensed on March 19, 2024.

Paragraph 18: Respondent Kim denies that she failed to notice the duration code and asserts that the Prescription directions included a duration with refills to follow. Nothing indicated that the Prescription was to be automatically refilled. As noted above, the system did not "terminate" the supply of levothyroxine, the Prescription was still active and could be refilled.

Paragraph 19: Respondents deny the factual allegations set forth in Paragraph 19.

Paragraph 20: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 20.

Paragraph 21: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 21.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 22.

Applicable Law: Paragraphs 23-28

Paragraph 23: Respondents agree that Paragraph 23 sufficiently reflects the contents of NRS 639.210(4).

Paragraph 24: Respondents agree that Paragraph 24 sufficiently reflects the contents of NAC 639.945(1)(d).

Paragraph 25: Respondents agree that Paragraph 25 sufficiently reflects the contents of NAC 639.945(1)(i).

Paragraph 26: Respondents agree that Paragraph 26 sufficiently reflects the contents of NAC 639.252(2).

Paragraph 27: Respondents agree that Paragraph 27 sufficiently reflects the contents of NAC 639.918.

Paragraph 28: Respondents agree that Paragraph 28 sufficiently reflects the contents of NRS 639.230(5), NAC 639.702, and NAC 639.945(3).

Count One (Paragraphs 29-35, Respondent Kim

Paragraph 29: Respondent Kim agrees that she verified Prescription no. 343217, which allowed three refills, not two as alleged. However, Respondent Kim denies the remaining allegations contained in Paragraph 29.

Paragraph 30: Respondent Kim does not work in the same location as the pharmacy technician who transcribed the information regarding the Prescription into the PharMerica computerized prescription management system, however Respondent Kim asserts that the technician did not incorrectly input the Prescription into the prescription management system. As described above, the prescription management system grabs the directions of the Prescription for generation of system codes. Regarding Prescription no. 343217, the physician's instructions included a duration and accordingly the system generated the appropriate code.

Paragraph 31: Respondent Kim denies the allegations contained in Paragraph 31 and contends that there was no error.

Paragraph 32: Respondent Kim agrees that she had a duty to strictly follow the instructions of the prescribing physician and that those instructions were indeed followed.

Paragraph 33: Respondent Kim denies the allegations contained in Paragraph 33.

Paragraph 34: Respondent Kim denies the allegations contained in Paragraph 34.

Paragraph 35: Paragraph 35 does not require a response from Respondent Kim.

Count Two (Paragraphs 36-38, Respondent PharMerica):

Paragraph 36: Respondent PharMerica denies the allegations contained in Paragraph 36.

Paragraph 37: Respondent PharMerica agrees it is responsible for Respondent Kim's conduct as an employed pharmacist but again denies that Respondent Kim engaged in unprofessional conduct as set forth in Paragraph 37.

Paragraph 38: Paragraph 38 does not require a substantive response from Respondent PharMerica.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Respondents reserve all legal defenses available to them in this matter.

Respondents further assert that no violation of NRS or NAC Chapters 639 has occurred in this matter. The Prescription was received on March 6, 2024, electronically and was properly entered into the PharMerica computerized prescription management system by a pharmacy technician. The technician appropriately entered the information into the prescription management system, including the duration which was included on the Prescription sent electronically by patient D.P.'s physician. Per the Prescription directions, the prescription management system entered a code of "X90D"; however, that did not terminate the Prescription at the end of 90-days but rather required a refill to be requested. The Prescription, as written, did not direct automatic refills. Respondents are without knowledge of why the nursing staff at MorningStar Senior Living failed to request the refill of levothyroxine, however Respondents assert that neither Respondent PharMerica nor Respondent Kim violated NRS/NAC Chapter 639 as alleged.

Respectfully submitted this 29th of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH02018,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondents.**	**Case Nos. 24-370-PH-N** **24-370-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (the "Board"), files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has jurisdiction over Respondent PharMerica ("Respondent PharMerica"), the holder of Pharmacy License No. PH02018, because Respondent PharMerica is licensed by the Board to operate a pharmacy at 4750 Longley Lane in Reno, Nevada.

2. The Board has jurisdiction over Respondent Camilla Kim, RPh ("Respondent Kim"), the holder of Certificate of Registration No. 19388, because Respondent Kim is registered by the Board to engage in the practice of pharmacy in Nevada.

FACTUAL ALLEGATIONS

3. Respondent PharMerica operates a pharmacy in Reno, Nevada.

4. In March 2024, Respondent Kim was employed by Respondent PharMerica as a pharmacist.

5. In 2023 and 2024, Respondent PharMerica was under contract with MorningStar Senior Living of Sparks ("MorningStar"), an assisted living facility, to dispense prescription medication and provide medication management services to residents of the MorningStar facility.

6. Respondent PharMerica worked cooperatively with the nursing staff at MorningStar to store and deliver prescription medications for the residents of the MorningStar facility.

7. In 2023 and 2024, patient D.P., an 87-year-old female, resided at MorningStar, where she received medication and medication management services from Respondent PharMerica.

8. In 2023 and 2024, patient D.P. required levothyroxine for hypothyroidism.

9. Between March 2023 and March 2024, Respondent PharMerica dispensed levothyroxine to patient D.P. without interruption, according to the instructions of patient D.P.'s physician.

10. On March 6, 2024, patient D.P.'s physician issued her a new prescription for levothyroxine. The prescription directed Respondent PharMerica to dispense an initial 90-day supply of levothyroxine with two refills.

11. On its face, the above prescription sufficed to meet patient D.P.'s medical needs for 12 months.

12. Patient D.P.'s physician electronically transmitted the above prescription to Respondent PharMerica.

13. Respondent PharMerica assigned no. 343217 to the above prescription. Per standard operating procedure, PharMerica processed prescription no. 343217 at its facility in Kentucky.

14. At the facility in Kentucky, a pharmaceutical technician transferred the information from the electronic prescription to a computerized prescription management system.

15. When transferring the prescription information, the technician incorrectly entered code "X90D" related to the "duration" of medication treatment. This code suppressed the automatic refill

function on the system, thus instructing the system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

16. Since patient D.P.'s levothyroxine was considered a "maintenance" medication, there should not have been a duration code associated with prescription no 343217.

17. In March 2024, before dispensing any medication under prescription no. 343217, Respondent Kim verified the prescription at PharMerica's facility in Reno.

18. When verifying the above prescription, Respondent Kim failed to notice that the duration code X90D, as described above, was inconsistent with the number of refill authorizations on the prescription itself. As noted above, this code instructed the automated system to terminate patient D.P.'s supply of levothyroxine after just 90 days.

19. In June of 2024, due to Respondent Kim's omission as described above, PharMerica failed to refill patient D.P.'s prescription for levothyroxine as directed by her physician.

20. Between June and September 2024, the nursing staff at MorningStar delivered no levothyroxine to patient D.P., and they made no inquiries of PharMerica concerning the abrupt cessation of patient D.P.'s medication treatment.

21. In August or September 2024, patient D.P.'s daughter observed that her mother's health had rapidly declined for no apparent reason. She alerted the nursing staff at MorningStar and/or patient D.P.'s physician.

22. In September 2024, Patient D.P. was admitted to the intensive care unit at Renown Hospital, where she was diagnosed with myxedema coma and cellulitis in her left leg. These medical conditions were caused by the cessation of medication treatment with levothyroxine.

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APPLICABLE LAW

23. The Board may discipline the holder of a license or registration issued by the Board if the holder engages in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Unprofessional conduct includes "failing strictly to follow the instructions of the person writing, making or ordering a prescription or chart order as to its filling or refilling." NAC 639.945(1)(d).

25. Unprofessional conduct includes performing one's duties as the holder of a certificate of registration issued by the Board in an "incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

26. A pharmacist has a duty to supervise a pharmaceutical technician who performs one or more of the functions necessary to prepare a prescription. NAC 639.252. This includes the duty to verify the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

27. A pharmacist has a duty to maintain a record of each refill of a prescription. NAC 639.918.

28. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of its employees. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

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COUNT ONE
Unprofessional Conduct by a Pharmacist
(Respondent Kim)

29. As alleged above, Respondent Kim verified prescription no. 343217 for levothyroxine, including two refills. In verifying the prescription, Respondent Kim failed to notice that a pharmaceutical technician in Kentucky had incorrectly entered a duration code into PharMerica's prescription management system, thus causing the system to suppress the automatic refill function.

30. Respondent Kim had a duty to supervise the pharmaceutical technician in Kentucky who performed data entry tasks related to prescription no. 343217.

31. Respondent Kim had a duty to correct the data entry error described above.

32. Respondent Kim had a duty to strictly follow the instructions of patient D.P.'s physician as to the refilling of no. 343217.

33. Respondent Kim performed the above duties in an incompetent, unskillful or negligent manner.

34. Due to Respondent Kim's unprofessional conduct as described above, patient D.P. suffered harm.

35. For her unprofessional conduct as described above Respondent Kim is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

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COUNT TWO
Employer Liability for Unprofessional Conduct
(Respondent PharMerica)

36. Respondent Kim engaged in unprofessional conduct as described above.

37. As Respondent Kim's employer at the time, Respondent PharMerica is responsible for the unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(3).

38. For said unprofessional conduct, Respondent PharMerica is subject to professional discipline pursuant to NRS 639.210(4) and NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Camilla Kim and the pharmacy license of Respondent PharMerica.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondent.**	**Case No. 24-370-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388,** **Respondent.**	**Case No. 24-370-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Camilla Kim, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

PharMerica
4750 Longley Ln #204
Reno, NV 89502

Camilla Kim, RPh
[redacted]
Reno, NV [redacted]

PharMerica
c/o Camilla Kim, RPh
4750 Longley Ln #204
Reno, NV 89502

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATORY

FILED
AUG 29 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PHARMERICA,** **Pharmacy License No. PH0218,** **and** **CAMILLA KIM, RPH,** **Certificate of Registration No. 19388.** **Respondents.**	**Case Nos. 24-370-PH- N** **24-370-RPH-N** **RESPONDENTS' ANSWER AND NOTICE OF DEFENSE**

Respondents PharMerica and Camilla Kim, RPH, hereby file with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on July 24, 2025.

ANSWER TO ACCUSATION

Jurisdiction: Paragraphs 1-2

Paragraph 1: Respondent PharMerica acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 1.

Paragraph 2: Respondent Kim acknowledges that the Board has jurisdiction in this matter as set forth in Paragraph 2.

Factual Allegations: Paragraphs 3-22

Paragraph 3: Respondent PharMerica acknowledges that it operates a pharmacy located in Reno, Nevada as set forth in Paragraph 3.

Paragraph 4: Respondent Kim acknowledges that she was employed by PharMerica in March 2024 as set forth in Paragraph 4.

Paragraph 5: Respondent PharMerica acknowledges that during the time periods set forth in Paragraph 5, it did dispense prescribed medication to residents of MorningStar Senior Living of Sparks as set forth in Paragraph 5.

Paragraph 6: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 6 to the extent the PharMerica coordinated deliveries of prescribed and dispensed medication to the nursing staff of MorningStar Senior Living.

Paragraph 7: Respondent PharMerica agrees that patient D.P. did receive some medication management services in the time frame noted in Paragraph 7.

Paragraph 8: Respondents are without sufficient personal knowledge to respond to the factual assertions contained in Paragraph 8.

Paragraph 9: Respondent PharMerica agrees with the factual assertions in Paragraph 9 to the extent that patient D.P. received levothyroxine in 2023 through the end of February 2024.

Paragraph 10: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 10 to the extent that a new prescription (no. 343217, the "Prescription") was issued March 6, 2024, by patient D.P.'s physician. However, the directions for the prescription were for one tablet daily for a 90-day duration with three refills, not two refills as noted in Paragraph 10 and further the prescription authorized three refills but did not direct automatic refills of the Prescription.

Paragraph 11: Respondents are without personal knowledge to substantively respond to the factual assertions set forth in Paragraph 11, however Respondents acknowledge that had the Prescription been refilled by patient D.P. as allowed, there would have been approximately twelve months of medication authorized by the physician.

Paragraph 12: Respondent PharMerica acknowledges that it received Prescription no. 343217 electronically.

Paragraph 13: Respondent PharMerica agrees with the factual assertions set forth in Paragraph 13.

Paragraph 14: Based on information and belief, Respondent PharMerica agrees that a PharMerica pharmacy technician would have transcribed the Prescription information into PharMerica's computerized prescription management system.

Paragraph 15: Respondents deny that the pharmacy technician incorrectly entered code "X90D" into the prescription management system. The technician correctly entered the Prescription and directions into the prescription management system; because the Prescription directions included a duration, the prescription management system automatically assigned the code to the Prescription. The prescription management system did not terminate D.P.'s supply of levothyroxine at the end of the initial ninety days; the Prescription was still active and simply needed to be refilled by MorningStar Senior Living.

Paragraph 16: Respondents disagree with the factual assertions contained in Paragraph 16; prescriptions, including prescriptions for "maintenance" medications, often have a duration associated with them.

Paragraph 17: Respondent Kim acknowledges that she verified Prescription no. 343217 before the Prescription was initially dispensed on March 19, 2024.

Paragraph 18: Respondent Kim denies that she failed to notice the duration code and asserts that the Prescription directions included a duration with refills to follow. Nothing indicated that the Prescription was to be automatically refilled. As noted above, the system did not "terminate" the supply of levothyroxine, the Prescription was still active and could be refilled.

Paragraph 19: Respondents deny the factual allegations set forth in Paragraph 19.

Paragraph 20: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 20.

Paragraph 21: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 21.

Paragraph 22: Respondents are without sufficient personal knowledge to respond to the factual allegations set forth in Paragraph 22.

Applicable Law: Paragraphs 23-28

Paragraph 23: Respondents agree that Paragraph 23 sufficiently reflects the contents of NRS 639.210(4).

Paragraph 24: Respondents agree that Paragraph 24 sufficiently reflects the contents of NAC 639.945(1)(d).

Paragraph 25: Respondents agree that Paragraph 25 sufficiently reflects the contents of NAC 639.945(1)(i).

Paragraph 26: Respondents agree that Paragraph 26 sufficiently reflects the contents of NAC 639.252(2).

Paragraph 27: Respondents agree that Paragraph 27 sufficiently reflects the contents of NAC 639.918.

Paragraph 28: Respondents agree that Paragraph 28 sufficiently reflects the contents of NRS 639.230(5), NAC 639.702, and NAC 639.945(3).

Count One (Paragraphs 29-35, Respondent Kim

Paragraph 29: Respondent Kim agrees that she verified Prescription no. 343217, which allowed three refills, not two as alleged. However, Respondent Kim denies the remaining allegations contained in Paragraph 29.

Paragraph 30: Respondent Kim does not work in the same location as the pharmacy technician who transcribed the information regarding the Prescription into the PharMerica computerized prescription management system, however Respondent Kim asserts that the technician did not incorrectly input the Prescription into the prescription management system. As described above, the prescription management system grabs the directions of the Prescription for generation of system codes. Regarding Prescription no. 343217, the physician's instructions included a duration and accordingly the system generated the appropriate code.

Paragraph 31: Respondent Kim denies the allegations contained in Paragraph 31 and contends that there was no error.

Paragraph 32: Respondent Kim agrees that she had a duty to strictly follow the instructions of the prescribing physician and that those instructions were indeed followed.

Paragraph 33: Respondent Kim denies the allegations contained in Paragraph 33.

Paragraph 34: Respondent Kim denies the allegations contained in Paragraph 34.

Paragraph 35: Paragraph 35 does not require a response from Respondent Kim.

Count Two (Paragraphs 36-38, Respondent PharMerica):

Paragraph 36: Respondent PharMerica denies the allegations contained in Paragraph 36.

Paragraph 37: Respondent PharMerica agrees it is responsible for Respondent Kim's conduct as an employed pharmacist but again denies that Respondent Kim engaged in unprofessional conduct as set forth in Paragraph 37.

Paragraph 38: Paragraph 38 does not require a substantive response from Respondent PharMerica.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Respondents reserve all legal defenses available to them in this matter.

Respondents further assert that no violation of NRS or NAC Chapters 639 has occurred in this matter. The Prescription was received on March 6, 2024, electronically and was properly entered into the PharMerica computerized prescription management system by a pharmacy technician. The technician appropriately entered the information into the prescription management system, including the duration which was included on the Prescription sent electronically by patient D.P.'s physician. Per the Prescription directions, the prescription management system entered a code of "X90D"; however, that did not terminate the Prescription at the end of 90-days but rather required a refill to be requested. The Prescription, as written, did not direct automatic refills. Respondents are without knowledge of why the nursing staff at MorningStar Senior Living failed to request the refill of levothyroxine, however Respondents assert that neither Respondent PharMerica nor Respondent Kim violated NRS/NAC Chapter 639 as alleged.

Respectfully submitted this 29th of August, 2025.

Lyn E. Beggs, Esq.
Attorney for Respondents

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

AMY TSENG, M.D.,
Certificate of Registration No. CS08125,

Respondent.

Case No. 24-484-CS-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Amy Tseng, M.D., ("Respondent"), because Respondent holds a certificate of registration issued by the Board authorizing her to prescribe controlled substances in Nevada.

2. The Board has jurisdiction over the subject matter of this accusation because it alleges violations involving the receipt, storage, possession, and/or distribution of dangerous drugs. As used herein, "dangerous drug" has the meaning ascribed to it in NRS 454.201.

FACTUAL ALLEGATIONS

3. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada.

4. Respondent holds certificate of registration no. CS08125, which was issued by the Board pursuant to NRS 453.226 and 453.231.

5. At all times alleged herein, Respondent was a "practitioner" as that term is defined at NRS 453.126, NRS 454.00958, and NRS 639.0125.

6. In 2024, Respondent maintained a medical practice at 2870 S. Jones Boulevard in Las Vegas, Nevada, where she offered cosmetic treatments for patients with aging and/or wrinkled skin. These included treatments with injectable neuromodulators derived from *Clostridium botulinum* (hereinafter "neuromodulators").

7. Neuromodulators are "dangerous drugs" as that term is defined at NRS 454.201.

8. On December 3, 2024, Respondent was in possession of neuromodulators ostensibly imported from drug manufacturers based in Turkey and South Korea. Their places of origin were evidenced by their packaging.

9. According to Respondent, who was questioned by Board Investigator Dena McClish, Respondent purchased some of the above dangerous drugs from a website called "ActivaDerma.com." Respondent stated that she had administered the drugs to her patients without complications.

10. Respondent stored the above dangerous drugs, among other drugs, at her office at 2870 S. Jones Boulevard in Las Vegas, Nevada.

11. According to Respondent, she typically administered neuromodulators marketed under the brand name "Xeomin." Respondent stated that some of her patients had requested "Dysport" instead of "Xeomin." For these patients, Respondent procured "Dysport" from the ActivaDerm.com website.

12. Dysport is manufactured in the United Kingdom by the French pharmaceutical company Ipsen. Dysport has been approved by the federal Food and Drug Administration ("FDA") for distribution in the United States.

13. On information and belief, the "Dysport" neuromodulators procured by Respondent were counterfeit insofar as they were not manufactured or distributed by Ipsen.

14. According to Respondent, she also acquired neuromodulators and other injectable drugs from a sales representative employed by a pharmaceutical company based in South Korea. These drugs were ostensibly marketed under the brand names "Hejeubo" and "Liporase."

15. On information and belief, Hejeubo is manufactured in South Korea and has not been approved by the FDA for distribution in the United States.

16. On information and belief, Liporase is manufactured in South Korea and has not been approved by the FDA for distribution in the United States.

17. On information and belief, ActivaDerma is not registered with the FDA to manufacture drugs or import drugs into the United States.

18. ActivaDerma is not licensed by the Board to sell drugs at wholesale in the state of Nevada.

19. In addition to being in possession of the dangerous drugs described above, including drugs labeled "Dysport," "Hejeubo" and "Liporase," Respondent was in possession of several pre-drawn syringes containing an unknown liquid substance. Respondent stated that the syringes contained Kenalog, also a dangerous drug.

20. Respondent stated that the syringes containing Kenalog were for her personal use. The syringes were not labeled.

21. On information and belief, Respondent did not acquire Kenalog pursuant to a prescription written by herself or another practitioner.

22. On information and belief, Kenalog was not dispensed to Respondent by a pharmacy or dispensing practitioner.

23. On information and belief, Respondent is not in possession of shipping documents, invoices, or other documents confirming the source of Kenalog allegedly acquired by Respondent for her personal use.

24. Respondent stored and/or possessed pre-drawn syringes allegedly containing Kenalog. Those syringes were not stock containers properly labeled and procured from a manufacturer, wholesaler or pharmacy.

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APPLICABLE LAW

25. The Board may revoke or suspend the registration of any practitioner who has violated or assisted in the violation of any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12); NRS 453.236.

26. It is unlawful to sell dangerous drugs at wholesale, or to permit dangerous drugs to be sold at wholesale, unless the seller holds a wholesaler license issued by the Board. NRS 639.100(1); NRS 639.233; NAC 639.593.

27. It is unlawful to introduce into interstate commerce, or to receive in interstate commerce any drug that is misbranded. 21 U.S.C.A § 331; NRS 454.351.

28. A drug is misbranded if its labeling is false or misleading in any particular. 21 U.S.C.A. § 352(a)(1).

29. A drug is misbranded if it was manufactured in an establishment not registered with the FDA, or if it was imported by a commercial importer of drugs not registered with the FDA. 21 U.S.C.A. § 352(o).

30. It is unlawful for any person to possess a dangerous drug for his or her personal use unless the drug was furnished to the person by a pharmacist or dispensing practitioner pursuant to a legal prescription. NRS 454.316.

31. It is unlawful for a physician to store dangerous drugs that are not in stock containers properly labeled and procured from a manufacturer, wholesaler or pharmacy. NRS 454.316.

32. A physician has a duty to refrain from administering drugs to her patients if those drugs are of unknown or questionable origin. *See* NRS 630.301(4) (physician may be disciplined for malpractice); 21 U.S.C.A. § 331 (physician may not receive misbranded drugs distributed in interstate commerce); NRS 454.351 (physician may not possess misbranded drugs distributed in interstate commerce); *see also Bourne v. Valdes*, 141 Nev.___, 569 P.3d 971, 974 (2025) (physician breaches standard of care when adverse drug reaction is a foreseeable consequence of drug therapy).

33. A physician has a duty to make reasonable inquiry concerning the source or origin or drugs procured for administration to patients. *See* NRS 630.301(4) (physician may be disciplined for malpractice); 21 U.S.C.A. § 331 (physician may not receive misbranded drugs distributed in interstate commerce); NRS 454.351 (physician may not possess misbranded drugs distributed in interstate commerce); *see also Bourne v. Valdes*, 141 Nev.___, 569 P.3d 971, 974 (2025) (physician breaches standard of care when adverse drug reaction is a foreseeable consequence of drug therapy).

34. The Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to public interest. NRS 639.210(4); NRS 453.236.

35. A practitioner's conduct is deemed unprofessional and contrary to public interest if the practitioner performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i).

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COUNT ONE
Dangerous Drugs Purchased from Activa.Derma.Com
(Negligence and/or Violations of State and/or Federal Law)

36. As alleged above, Respondent purchased dangerous drugs from the ActivaDerma.com website.

37. ActivaDerma.com was not licensed by the Board to sell dangerous drugs at wholesale.

38. Based upon the facts and circumstances surrounding her dealings with ActivaDerma.com, Respondent knew or should have known that ActivaDerma.com was not licensed by the Board to sell dangerous drugs at wholesale.

39. Based upon the facts and circumstances surrounding her dealings with ActivaDerma.com, Respondent knew or should have known that ActivaDerma.com was not a safe or reputable supplier of dangerous drugs.

40. By purchasing dangerous drugs from the ActivaDerma.com website, Respondent assisted or permitted the unlicensed wholesale distribution of drugs in violation of NRS 639.100(1).

41. By purchasing dangerous drugs from the ActivaDerma.com website, Respondent received and/or possessed misbranded drugs in violation of 21 U.S.C.A § 331 and/or NRS 454.351.

42. By purchasing dangerous drugs from the ActivaDerma.com website, Respondent breached her duty as a physician to procure drugs from a known, reputable source, thus performing her duties as the holder of a registration issued by the Board in a negligent, unskillful, or incompetent manner.

43. Respondent's acts and/or omissions as alleged above amount to a violation of state law and/or federal law relating to the distribution of drugs, such that the Board may impose administrative discipline. NRS 630.210(12); NRS 453.236(1)(e); NRS 453.231(1)(b).

44. Respondent's acts and/or omissions as alleged above were unprofessional and/or contrary to the public interest, such that the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236(1)(e); NRS 453.231(1)(h); NAC 639.945(1)(i).

COUNT TWO
Dangerous Drugs Acquired from Unknown Person (Negligence and/or Violations of State and/or Federal Law)

45. As alleged above, Respondent acquired dangerous drugs from an unknown pharmaceutical sales agent or representative.

46. The unknown pharmaceutical sales agent or representative was not licensed by the Board to sell or distribute dangerous drugs at wholesale.

47. Based upon the facts and circumstances surrounding her dealings with the unknown pharmaceutical sales agent or representative, Respondent knew or should have known that he was not licensed by the Board to sell or distribute dangerous drugs at wholesale.

48. Based upon the facts and circumstances surrounding her dealings with the unknown pharmaceutical sales agent or representative, Respondent knew or should have known that he was not a safe or reputable supplier of dangerous drugs.

49. By acquiring dangerous drugs from an unknown pharmaceutical sales agent or representative, Respondent assisted or permitted the unlicensed wholesale distribution of drugs in violation of NRS 639.100(1).

50. By acquiring dangerous drugs from an unknown pharmaceutical sales agent or representative, Respondent received and/or possessed misbranded drugs in violation of 21 U.S.C.A § 331 and/or NRS 454.351.

51. By acquiring dangerous drugs from an unknown pharmaceutical sales agent or representative, Respondent breached her duty as a physician to procure drugs from a known, reputable source, thus performing her duties as the holder of a registration issued by the Board in a negligent, unskillful, or incompetent manner.

52. Respondent's acts and/or omissions as alleged above amount to a violation of state law and/or federal law relating to the distribution of drugs, such that the Board may impose administrative discipline. NRS 630.210(12); NRS 453.236(1)(e); NRS 453.231(1)(b).

53. Respondent's acts and/or omissions as alleged above were unprofessional and/or contrary to the public interest, such that the Board may impose administrative discipline. NRS 639.210(4); NRS 453.236(1)(e); NRS 453.231(1)(h); NAC 639.945(1)(i).

COUNT THREE
Unlawful Possession of Dangerous Drugs for Personal Use

54. As alleged above, Respondent stored and/or possessed pre-drawn syringes allegedly containing Kenalog. Those syringes were not stock containers properly labeled and procured from a manufacturer, wholesaler or pharmacy.

55. According to Respondent, the pre-drawn syringes containing Kenalog were for her personal use.

56. As alleged above, Respondent did not acquire Kenalog pursuant to a prescription written by herself or another practitioner.

57. As alleged above, Kenalog was not dispensed to Respondent by a pharmacy or dispensing practitioner.

58. Given the above facts and circumstances, it was unlawful for Respondent to possess Kenalog, a dangerous drug.

59. Respondent's conduct as alleged above violated NRS 454.316, such that Respondent is subject to administrative discipline. NRS 630.210(12); NRS 453.236(1)(e); NRS 453.231(1)(b).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Amy Tseng.

DATED this 23rd day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMY TSENG, M.D.,** **Certificate of Registration No. CS08125,** **Respondent.**	**Case No. 24-484-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMY TSENG, M.D.,** **Certificate of Registration No. CS08125,** **Respondent.**	**Case No. 24-484-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Amy Tseng, M.D.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of October 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Amy Tseng, M.D.
2870 S Jones Blvd Ste 1
Las Vegas, NV 89146

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD OF PHARMACY

CLARK HILL PLLC
CRANE M. POMERANTZ
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1700 South Pavilion Center Drive, Suite 500
Las Vegas, Nevada 89135
Tel: (702) 862-8300
Fax: (702) 778-9709

Attorneys for Amy Tseng, M.D.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. AMY TSENG, M.D., Certificate of Registration No. CS08125, Respondent.	CASE NO.: 24-484-CS-S **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-titled matter before the Nevada States Board of Pharmacy (the "Board"), declares:

1. That her objections to the Notice of Intended Action and Accusation (the "Notice") as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

a. This action is barred by the doctrine of laches. The Notice addresses information it purports to have obtained during a search of Respondent's office on December 3, 2024, relating to conduct that occurred prior to that. Dr. Tseng addressed the conduct in a detailed letter dated December 30, 2024 to the Board's investigator. The Board filed its Complaint on October 23, 2025, approximately eleven (11) months after its search of Respondent's office and far longer after the alleged conduct, without a valid excuse for such delay, as a result of which Dr. Tseng was prejudiced. Implicit in the Board's statutes (NRS 639.241, *et. seq.*) and its regulations (NAC 639.120, *et. seq.*) is an obligation to proceed

promptly and fairly against Respondent. Because the Board did not promptly make a determination as to whether the Notice would be filed against Dr. Tseng, it would be inequitable and unjust to proceed.

b. The Notice is impermissibly vague, as it repeatedly makes allegations "on information and belief." The due process principles that apply in disciplinary proceedings require that such proceedings be fundamentally fair and afford the respondent attorney a meaningful opportunity to defend against the charges. *See In re Ruffalo*, 390 U.S. 544, 550-51, 88 S.Ct. 1222, 1225-26 (1968) (attorney disciplinary proceedings are "adversary proceedings of a quasi-criminal nature" because a punishment or penalty can be imposed on the licensee, and therefore, entitles the licensee to due process). Allegations "on information and belief" are unconstitutionally vague, deprive Respondent of a meaningful opportunity to respond, and impermissibly shifts the burden from the Board to the Respondent.

c. Respondent steadfastly denies that she ever knowingly or intentionally: (a) received or possessed misbranded drugs in violation of 21 U.S.C.A. § 331 and/or NRS 454.351; (b) assisted or permitted the unlicensed wholesale distribution of drugs in violation fo NRS 639.100(1); or (3) unlawfully possessed Kenalog, a dangerous drug.

d. At the time Dr Tseng purchased a small amount of Dysport through the ActivaDerma website, she did not know it was manufactured in a foreign country and there were no indicia, in the purchasing process that Dysport obtained from ActivaDerma that was allegedly "misbranded".

2. That, in answer to the Notice of Intended Action and Accusation, she admits, denies, and alleges as follows:

a. Respondent admits that the Board has jurisdiction over this matter.

b. Respondent admits the allegations in Paragraphs 2 through 6 of the Notice of Intended Action (the "Notice").

c. The allegations in Paragraph 7 contains a conclusion of law for which no response is required.

d. The allegations in Paragraph 8 are vague due to the use of the word "ostensibly." Because Respondent cannot respond adequately to these allegations, she denies them.

e. Respondent admits the allegations in Paragraph 9 through 12 of the Notice.

f. Respondent denies the allegations in Paragraph 13 of the Notice.

g. Respondent admits the allegations in Paragraph 14 of the Notice.

h. The allegations in Paragraphs 15 through 18 contain conclusions of law for which no response is required.

i. Respondent admits the allegations in Paragraphs 19 and 20.

j. Respondent denies the allegations in Paragraphs 21 through 24.

k. The allegations in Paragraphs 25 through 35 contain conclusions of law for which no response is required.

l. For the reasons set forth in her objections, and based on her admissions and denials of the allegations in the preceding paragraphs, Respondent denies the allegations in Counts One through Three.

k. Respondent hereby declares, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to best of my knowledge.

Dated this 4th day of November 2025.

Amy Tseng, MD

CLARK HILL PLC

By */s/ Crane Pomerantz*
Crane M. Pomerantz
Nevada Bar No. 14103
1700 S. Pavilion Center Drive, Suite 500
Las Vegas, Nevada 89135

Attorneys for Respondent

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of Clark Hill PLC, and that on the 5th day of November 2025, I caused to be served a true and correct copy of the foregoing **Answer and Notice of Defense** in the following manner:

The above-referenced document was emailed to the Board's coordinating staff and its prosecuting attorney at the following addresses: TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov.

/s/ Jamie Soquena
An Employee of CLARK HILL PLC

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CVS PHARMACY #6717,
Pharmacy License No. PH01932,

ANALEAH PRESBITERO, RPH,
Certificate of Registration No. 23353, and

TODD SPEARS, RPH,
Certificate of Registration No. 18123,

Respondents.

CASE NOS. 24-013-PH-S
24-013-RPH-A-S
24-013-RPH-B-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Analeah Presbitero, RPh (Presbitero), Certificate of Registration No. 23353, and Respondent Todd Spears, RPh (Spears), Certificate of Registration No. 18123, were pharmacists registered with the Board, and Respondent CVS Pharmacy #6717, Pharmacy License No. PH01932, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Presbitero was employed as managing pharmacist of CVS Pharmacy #6717, located at 60 N. Valle Verde Drive in Henderson, and Spears was employed as a pharmacist at CVS Pharmacy #6717 at the time of the events alleged herein.

3. On January 3, 2024, CVS Pharmacy #6717 received a prescription for 30 escitalopram 20 mg tablets from prescriber G.W. for patient J.F. The CVS pharmacy computer system designated this prescription no. 1223493.

4. Also on January 3, 2024, CVS Pharmacy #6717 received a prescription for 90 tramadol HCl 50mg tablets from prescriber S.J. for patient T.B. The CVS pharmacy computer system designated this prescription no. 1223500.

5. On January 3, 2024, Jasmine Harshman (Harshman), a pharmaceutical technician, concurrently prepared prescription no. 1223493 for escitalopram and prescription no. 1223500 for tramadol.

6. When preparing prescription no. 1223493, Harshman poured the escitalopram tablets from a stock bottle, counted them according to the number prescribed, and then placed them in an unlabeled amber vial.

7. When preparing prescription no. 1223500, Harshman poured the tramadol tablets from a stock bottle, counted them according to the number prescribed, and then placed them in an unlabeled amber vial.

8. Harshman recalls that she placed an amber vial atop one of the printed labels that she was preparing to affix to the vial. According to Harshman, the amber vial containing escitalopram was likely pushed off its corresponding label, and when she handled it again, she inadvertently placed it atop the label designated for prescription no. 1223500.

9. At some point after Harshman first handled prescription nos. 1223493 and 1223500, the label for the escitalopram was mistakenly affixed to the amber vial containing tramadol.

10. At some point after Harshman first handled prescription nos. 1223493 and 1223500, the label for the tramadol was mistakenly affixed to the amber vial containing escitalopram.

11. Harshman used the CVS accuracy scan technology when preparing the above prescriptions.

12. For example, in preparing the prescription for escitalopram, Harshman snapped a photographic image of the escitalopram tablets on the counting tray, she scanned the manufacturer's data associated with the stock bottle containing the escitalopram, and then she scanned the label that she had prepared to affix to the amber vial. This created a digital file that correlated the escitalopram product image with the escitalopram product information.

13. On January 3, 2024, using the accuracy scan technology described above, Presbitero performed final verification of prescription no. 1223493. In this regard, Presbitero viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with escitalopram. Presbitero did not directly inspect the amber vial or its contents. Had she done so, she would have seen that the amber vial contained 90 tablets of tramadol.

14. On January 3, 2024, using the accuracy scan technology described above, Presbitero performed final verification of prescription no. 1223500. In this regard, Presbitero viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with tramadol. Presbitero did not directly inspect the amber vial or its contents. Had she done so, she would have seen that the amber vial contained 30 tablets of escitalopram.

15. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists, including Presbitero and Spears, to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients.

16. On information and belief, it became standard operating procedure for the pharmacists employed by CVS #6717 to use the accuracy scan technology as a substitute for a

direct visual inspection of the drugs that they dispensed to their patients. CVS #6717 actively encouraged adherence to this standard operating procedure.

17. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists to use the accuracy scan technology as a means of meeting production goals that would not otherwise have been met if pharmacists had performed a direct visual inspection of the drugs that they dispensed.

18. On January 4, 2024, CVS #6717 dispensed prescription no. 122493.

19. On or about January 31, 2024, patient J.F. called and returned to CVS #6717 carrying 19 tablets of tramadol in a plastic bag. Patient J.F. explained that she had received the wrong medication, and after an internal investigation, CVS #6717 confirmed that it had dispensed tramadol to patient J.F. instead of escitalopram, as prescribed.

20. Patient J.F. ingested eight tramadol tablets before she noticed the error and experienced drowsiness and hallucinations.

21. On January 5, 2024, CVS #6717 dispensed prescription no. 1223500. Patient T.B. picked up the prescription and immediately returned to the pharmacy because she noticed that she had only received 30 tablets instead of 90.

22. Although patient T.B. promptly returned to the pharmacy to complain about the tablet count, patient T.B. failed to notice that the tablets were escitalopram, not tramadol as prescribed.

23. Spears was the pharmacist on duty on January 5, 2024, when patient T.B. returned to the pharmacy to correct her tablet count. A pharmaceutical technician on duty at the time poured the 30 tablets into the pill counter and notified Spears of the 60-tablet shortage. Spears did not view the bottle or tablets. Another technician added 60 tablets of tramadol to the machine. All 90 tablets were then placed back into the amber vial and the technician handed it back to patient T.B.

24. After the patient had left the pharmacy, Spears viewed the original product image of the tablets associated with prescription no. 1223500. The image showed that patient T.B.'s prescription contained 90 tablets of tramadol, as opposed to the 30 tablets of escitalopram and 60 tablets of tramadol that were ultimately dispensed to her. Spears did not document the shortage, and he did not perform any further investigation.

25. Patient T.B. ingested all the medication in the amber vial for prescription no. 1223500.

26. Patient T.B. reported feeling more pain than usual, weight gain, and migraines.

27. On information and belief, patient T.B. ingested at least 30 tablets of the escitalopram that had been prescribed for patient J.F.

APPLICABLE LAW

28. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d).

29. Unprofessional conduct also includes a registrant or licensee performing duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

30. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702. Such a pharmacist must verify, among other things, the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

31. A pharmaceutical technician may perform one or more of the functions necessary to prepare a prescription only if the supervising pharmacist inspects the final product. NAC 639.245(2).

32. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Presbitero)

33. Presbitero engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she performed final verifications for prescription no. 1223493 and prescription no. 1223500 and failed to observe that the tablets in each of the amber vials did not correlate with the labels on each of the amber vials.

34. Having performed her duties in incompetent, unskillful, or negligent manner, as described above, Presbitero is subject to discipline pursuant to NRS 639.210(4).

COUNT TWO

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Spears)

35. Spears engaged in unprofessional conduct, as defined in NAC 639.945(1)(d) and (i), when he failed to perceive and correct the error in prescription no. 1223500 after patient T.B. returned with a complaint about the tablet count.

36. Although patient T.B. ultimately left the pharmacy with 90 tablets, including 60 tablets of tramadol, patient T.B. remained unaware that 30 of those tablets were never prescribed for her.

37. After becoming aware of the patient's complaint about the tablet count, Spears delegated to a pharmaceutical technician the responsibility to investigate and correct the discrepancy. Had Spears visually inspected the tablets, as opposed to a product image of the

tablets, he would have seen that the amber vial contained escitalopram instead of tramadol as indicated on the label.

38. Furthermore, Spears engaged in unprofessional conduct, as defined in NAC 639.945(1)(i), when he failed to investigate why patient T.B. received 30 tablets instead of 90 as prescribed.

39. Having performed his duties in incompetent, unskillful, or negligent manner, as described above, Spears is subject to discipline pursuant to NRS 639.210(4).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent CVS #6717)

40. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent CVS #6717 is responsible for those violations, including all errors and omissions of Respondents Presbitero, Spears, and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1223493 and prescription no. 1223500.

41. Due to the unprofessional conduct of Presbitero, Spears, and/or other of its employees, CVS #6717 is subject to professional discipline pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

COUNT FOUR
Performing Duties in a Negligent Manner
(Respondent CVS #6717)

42. As alleged above, CVS #6717, acting through its corporate officers and managers, directed its pharmacists, including Presbitero and Spears, to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients.

43. As alleged above, it became standard operating procedure for the pharmacists employed by CVS #6717 to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients. CVS #6717 actively encouraged adherence to this standard operating procedure.

44. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists to use the accuracy scan technology as a means of meeting production goals that would not otherwise have been met if pharmacists had performed a direct visual inspection of the drugs that they dispensed.

45. Pursuant to NAC 639.245 and NAC 639.252, CVS #6717 had a duty to ensure that its pharmacists performed a direct visual inspection of the drugs that they dispensed.

46. Acting through its officers and managers, CVS #6717 fostered a work environment in which its pharmacists were actively discouraged from performing a direct visual inspection of the drugs that they dispensed.

47. In light of the foregoing, CVS #6717 performed its duties as a licensee in an incompetent, unskillful, or negligent manner.

48. Due to its unprofessional conduct as alleged above, CVS #6717 caused prescription no. 1223493 and prescription no. 1223500 to be erroneously filled.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificates of registration of these Respondents.

Signed this 11th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #6717,** **Pharmacy License No. PH01932,** **Respondent.**	**Case No. 24-013-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #6717,** **Pharmacy License No. PH01932,** **Respondent.**	**Case No. 24-013-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR
CVS Pharmacy #6717

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

Analeah Presbitero, RPh
[redacted]
Las Vegas, NV [redacted]

Todd Spears, RPh
[redacted]
Henderson, NV [redacted]

Todd Spears, RPh
[redacted]
Henderson, NV [redacted]

Todd Spears, RPh
c/o CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

CVS Pharmacy #6717
c/o Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

Analeah Presbitero, RPh
c/o CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CVS PHARMACY #6717,
Pharmacy License No. PH01932,

ANALEAH PRESBITERO, RPH,
Certificate of Registration No. 23353, and

TODD SPEARS, RPH,
Certificate of Registration No. 18123,

Respondents.

CASE NOS. 24-013-PH-S
24-013-RPH-A-S
24-013-RPH-B-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Analeah Presbitero, RPh (Presbitero), Certificate of Registration No. 23353, and Respondent Todd Spears, RPh (Spears), Certificate of Registration No. 18123, were pharmacists registered with the Board, and Respondent CVS Pharmacy #6717, Pharmacy License No. PH01932, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Presbitero was employed as managing pharmacist of CVS Pharmacy #6717, located at 60 N. Valle Verde Drive in Henderson, and Spears was employed as a pharmacist at CVS Pharmacy #6717 at the time of the events alleged herein.

3. On January 3, 2024, CVS Pharmacy #6717 received a prescription for 30 escitalopram 20 mg tablets from prescriber G.W. for patient J.F. The CVS pharmacy computer system designated this prescription no. 1223493.

4. Also on January 3, 2024, CVS Pharmacy #6717 received a prescription for 90 tramadol HCl 50mg tablets from prescriber S.J. for patient T.B. The CVS pharmacy computer system designated this prescription no. 1223500.

5. On January 3, 2024, Jasmine Harshman (Harshman), a pharmaceutical technician, concurrently prepared prescription no. 1223493 for escitalopram and prescription no. 1223500 for tramadol.

6. When preparing prescription no. 1223493, Harshman poured the escitalopram tablets from a stock bottle, counted them according to the number prescribed, and then placed them in an unlabeled amber vial.

7. When preparing prescription no. 1223500, Harshman poured the tramadol tablets from a stock bottle, counted them according to the number prescribed, and then placed them in an unlabeled amber vial.

8. Harshman recalls that she placed an amber vial atop one of the printed labels that she was preparing to affix to the vial. According to Harshman, the amber vial containing escitalopram was likely pushed off its corresponding label, and when she handled it again, she inadvertently placed it atop the label designated for prescription no. 1223500.

9. At some point after Harshman first handled prescription nos. 1223493 and 1223500, the label for the escitalopram was mistakenly affixed to the amber vial containing tramadol.

10. At some point after Harshman first handled prescription nos. 1223493 and 1223500, the label for the tramadol was mistakenly affixed to the amber vial containing escitalopram.

11. Harshman used the CVS accuracy scan technology when preparing the above prescriptions.

12. For example, in preparing the prescription for escitalopram, Harshman snapped a photographic image of the escitalopram tablets on the counting tray, she scanned the manufacturer's data associated with the stock bottle containing the escitalopram, and then she scanned the label that she had prepared to affix to the amber vial. This created a digital file that correlated the escitalopram product image with the escitalopram product information.

13. On January 3, 2024, using the accuracy scan technology described above, Presbitero performed final verification of prescription no. 1223493. In this regard, Presbitero viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with escitalopram. Presbitero did not directly inspect the amber vial or its contents. Had she done so, she would have seen that the amber vial contained 90 tablets of tramadol.

14. On January 3, 2024, using the accuracy scan technology described above, Presbitero performed final verification of prescription no. 1223500. In this regard, Presbitero viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with tramadol. Presbitero did not directly inspect the amber vial or its contents. Had she done so, she would have seen that the amber vial contained 30 tablets of escitalopram.

15. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists, including Presbitero and Spears, to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients.

16. On information and belief, it became standard operating procedure for the pharmacists employed by CVS #6717 to use the accuracy scan technology as a substitute for a

direct visual inspection of the drugs that they dispensed to their patients. CVS #6717 actively encouraged adherence to this standard operating procedure.

17. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists to use the accuracy scan technology as a means of meeting production goals that would not otherwise have been met if pharmacists had performed a direct visual inspection of the drugs that they dispensed.

18. On January 4, 2024, CVS #6717 dispensed prescription no. 122493.

19. On or about January 31, 2024, patient J.F. called and returned to CVS #6717 carrying 19 tablets of tramadol in a plastic bag. Patient J.F. explained that she had received the wrong medication, and after an internal investigation, CVS #6717 confirmed that it had dispensed tramadol to patient J.F. instead of escitalopram, as prescribed.

20. Patient J.F. ingested eight tramadol tablets before she noticed the error and experienced drowsiness and hallucinations.

21. On January 5, 2024, CVS #6717 dispensed prescription no. 1223500. Patient T.B. picked up the prescription and immediately returned to the pharmacy because she noticed that she had only received 30 tablets instead of 90.

22. Although patient T.B. promptly returned to the pharmacy to complain about the tablet count, patient T.B. failed to notice that the tablets were escitalopram, not tramadol as prescribed.

23. Spears was the pharmacist on duty on January 5, 2024, when patient T.B. returned to the pharmacy to correct her tablet count. A pharmaceutical technician on duty at the time poured the 30 tablets into the pill counter and notified Spears of the 60-tablet shortage. Spears did not view the bottle or tablets. Another technician added 60 tablets of tramadol to the machine. All 90 tablets were then placed back into the amber vial and the technician handed it back to patient T.B.

24. After the patient had left the pharmacy, Spears viewed the original product image of the tablets associated with prescription no. 1223500. The image showed that patient T.B.'s prescription contained 90 tablets of tramadol, as opposed to the 30 tablets of escitalopram and 60 tablets of tramadol that were ultimately dispensed to her. Spears did not document the shortage, and he did not perform any further investigation.

25. Patient T.B. ingested all the medication in the amber vial for prescription no. 1223500.

26. Patient T.B. reported feeling more pain than usual, weight gain, and migraines.

27. On information and belief, patient T.B. ingested at least 30 tablets of the escitalopram that had been prescribed for patient J.F.

APPLICABLE LAW

28. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d).

29. Unprofessional conduct also includes a registrant or licensee performing duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

30. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702. Such a pharmacist must verify, among other things, the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

31. A pharmaceutical technician may perform one or more of the functions necessary to prepare a prescription only if the supervising pharmacist inspects the final product. NAC 639.245(2).

32. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Presbitero)

33. Presbitero engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she performed final verifications for prescription no. 1223493 and prescription no. 1223500 and failed to observe that the tablets in each of the amber vials did not correlate with the labels on each of the amber vials.

34. Having performed her duties in incompetent, unskillful, or negligent manner, as described above, Presbitero is subject to discipline pursuant to NRS 639.210(4).

COUNT TWO

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Spears)

35. Spears engaged in unprofessional conduct, as defined in NAC 639.945(1)(d) and (i), when he failed to perceive and correct the error in prescription no. 1223500 after patient T.B. returned with a complaint about the tablet count.

36. Although patient T.B. ultimately left the pharmacy with 90 tablets, including 60 tablets of tramadol, patient T.B. remained unaware that 30 of those tablets were never prescribed for her.

37. After becoming aware of the patient's complaint about the tablet count, Spears delegated to a pharmaceutical technician the responsibility to investigate and correct the discrepancy. Had Spears visually inspected the tablets, as opposed to a product image of the

tablets, he would have seen that the amber vial contained escitalopram instead of tramadol as indicated on the label.

38. Furthermore, Spears engaged in unprofessional conduct, as defined in NAC 639.945(1)(i), when he failed to investigate why patient T.B. received 30 tablets instead of 90 as prescribed.

39. Having performed his duties in incompetent, unskillful, or negligent manner, as described above, Spears is subject to discipline pursuant to NRS 639.210(4).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent CVS #6717)

40. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent CVS #6717 is responsible for those violations, including all errors and omissions of Respondents Presbitero, Spears, and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1223493 and prescription no. 1223500.

41. Due to the unprofessional conduct of Presbitero, Spears, and/or other of its employees, CVS #6717 is subject to professional discipline pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

COUNT FOUR
Performing Duties in a Negligent Manner
(Respondent CVS #6717)

42. As alleged above, CVS #6717, acting through its corporate officers and managers, directed its pharmacists, including Presbitero and Spears, to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients.

43. As alleged above, it became standard operating procedure for the pharmacists employed by CVS #6717 to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients. CVS #6717 actively encouraged adherence to this standard operating procedure.

44. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists to use the accuracy scan technology as a means of meeting production goals that would not otherwise have been met if pharmacists had performed a direct visual inspection of the drugs that they dispensed.

45. Pursuant to NAC 639.245 and NAC 639.252, CVS #6717 had a duty to ensure that its pharmacists performed a direct visual inspection of the drugs that they dispensed.

46. Acting through its officers and managers, CVS #6717 fostered a work environment in which its pharmacists were actively discouraged from performing a direct visual inspection of the drugs that they dispensed.

47. In light of the foregoing, CVS #6717 performed its duties as a licensee in an incompetent, unskillful, or negligent manner.

48. Due to its unprofessional conduct as alleged above, CVS #6717 caused prescription no. 1223493 and prescription no. 1223500 to be erroneously filled.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificates of registration of these Respondents.

Signed this 11th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ANALEAH PRESBITERO, RPH,** **Certificate of Registration No. 23353,** **Respondent.**	**Case No. 24-013-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ANALEAH PRESBITERO, RPH,** **Certificate of Registration No. 23353,** **Respondent.**	**Case No. 24-013-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Analeah Presbitero, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

Analeah Presbitero, RPh
[redacted]
Las Vegas, NV [redacted]

Todd Spears, RPh
[redacted]
Henderson, NV [redacted]

Todd Spears, RPh
[redacted]
Henderson, NV [redacted]

Todd Spears, RPh
c/o CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

CVS Pharmacy #6717
c/o Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

Analeah Presbitero, RPh
c/o CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #6717,** **Pharmacy License No. PH01932,** **ANALEAH PRESBITERO, RPH,** **Certificate of Registration No. 23353, and** **TODD SPEARS, RPH,** **Certificate of Registration No. 18123,** **Respondents.**	**Case No.** **24-013-PH-S** **24-013-RPH-A-S** **24-013-RPH-B-S** **STIPULATION AND ORDER** **[ANALEAH PRESBITERO ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Analeah Presbitero, RPH, Certificate of Registration No. 23353, ("Respondent"), by and through counsel, Roger N. Morris, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondent acknowledges that she understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that she has executed it knowingly and voluntarily.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter

233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One of the Accusation, to wit:

A. On January 3, 2024, CVS #6717 received a prescription for 30 escitalopram 20 mg tablets. The CVS pharmacy computer system designated this prescription no. 1223493.

B. Also on January 3, 2024, CVS #6717 received a prescription for 90 tramadol HCl 50mg tablets. The CVS pharmacy computer system designated this prescription no. 1223500.

C. On January 3, 2024, a pharmaceutical technician prepared prescription no. 1223493 for escitalopram and prescription no. 1223500 for tramadol.

D. According to the pharmaceutical technician, at some point after the pharmaceutical technician first handled prescription nos. 1223493 and 1223500, the label for the escitalopram was mistakenly affixed to the amber vial containing tramadol, and the label for the tramadol was mistakenly affixed to the amber vial containing escitalopram.

E. The pharmaceutical technician used the CVS virtual verification process and technology when preparing the above prescriptions.

F. On January 3, 2024, using the accuracy scan technology described above, Respondent performed final verification of prescription no. 1223493. In this regard, Respondent viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with escitalopram.

G. On January 3, 2024, using the virtual verification process and technology described above, Respondent performed final verification of prescription no. 1223500. In this regard, Respondent viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with tramadol.

H. Prescription no. 1223493 for escitalopram was dispensed to the patient containing tramadol instead of escitalopram.

I. Prescription no. 1223500 was dispensed to the patient containing only 30 tablets, which were likely escitalopram instead of tramadol.

8. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **Five Hundred and 00/100 Dollars ($500.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-013-RPH-A-S. However, Respondent understands and acknowledges that her failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by

Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____ 2026.

_____
ANNALEAH PRESBITERO, RPH
Certificate of Registration No. 23353

Signed this ____ day of _____ 2026.
Nevada State Board of Pharmacy

By_____
LAURA M. TUCKER, ESQ.
General Counsel

Approved as to Form and Content:

_____
ROGER N. MORRIS, ESQ.

Attorney for Respondent Annaleah Presbitero, RPH

DECISION AND ORDER

As to Annaleah Presbitero, in Case No. 24-013-RPH-A-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of March 2026.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #6717,** **Pharmacy License No. PH01932,** **ANALEAH PRESBITERO, RPH,** **Certificate of Registration No. 23353, and** **TODD SPEARS, RPH,** **Certificate of Registration No. 18123,** **Respondents.**	**CASE NOS. 24-013-PH-S** **24-013-RPH-A-S** **24-013-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Analeah Presbitero, RPh (Presbitero), Certificate of Registration No. 23353, and Respondent Todd Spears, RPh (Spears), Certificate of Registration No. 18123, were pharmacists registered with the Board, and Respondent CVS Pharmacy #6717, Pharmacy License No. PH01932, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Presbitero was employed as managing pharmacist of CVS Pharmacy #6717, located at 60 N. Valle Verde Drive in Henderson, and Spears was employed as a pharmacist at CVS Pharmacy #6717 at the time of the events alleged herein.

3. On January 3, 2024, CVS Pharmacy #6717 received a prescription for 30 escitalopram 20 mg tablets from prescriber G.W. for patient J.F. The CVS pharmacy computer system designated this prescription no. 1223493.

4. Also on January 3, 2024, CVS Pharmacy #6717 received a prescription for 90 tramadol HCl 50mg tablets from prescriber S.J. for patient T.B. The CVS pharmacy computer system designated this prescription no. 1223500.

5. On January 3, 2024, Jasmine Harshman (Harshman), a pharmaceutical technician, concurrently prepared prescription no. 1223493 for escitalopram and prescription no. 1223500 for tramadol.

6. When preparing prescription no. 1223493, Harshman poured the escitalopram tablets from a stock bottle, counted them according to the number prescribed, and then placed them in an unlabeled amber vial.

7. When preparing prescription no. 1223500, Harshman poured the tramadol tablets from a stock bottle, counted them according to the number prescribed, and then placed them in an unlabeled amber vial.

8. Harshman recalls that she placed an amber vial atop one of the printed labels that she was preparing to affix to the vial. According to Harshman, the amber vial containing escitalopram was likely pushed off its corresponding label, and when she handled it again, she inadvertently placed it atop the label designated for prescription no. 1223500.

9. At some point after Harshman first handled prescription nos. 1223493 and 1223500, the label for the escitalopram was mistakenly affixed to the amber vial containing tramadol.

10. At some point after Harshman first handled prescription nos. 1223493 and 1223500, the label for the tramadol was mistakenly affixed to the amber vial containing escitalopram.

11. Harshman used the CVS accuracy scan technology when preparing the above prescriptions.

12. For example, in preparing the prescription for escitalopram, Harshman snapped a photographic image of the escitalopram tablets on the counting tray, she scanned the manufacturer's data associated with the stock bottle containing the escitalopram, and then she scanned the label that she had prepared to affix to the amber vial. This created a digital file that correlated the escitalopram product image with the escitalopram product information.

13. On January 3, 2024, using the accuracy scan technology described above, Presbitero performed final verification of prescription no. 1223493. In this regard, Presbitero viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with escitalopram. Presbitero did not directly inspect the amber vial or its contents. Had she done so, she would have seen that the amber vial contained 90 tablets of tramadol.

14. On January 3, 2024, using the accuracy scan technology described above, Presbitero performed final verification of prescription no. 1223500. In this regard, Presbitero viewed the digital file, including the product image, and concluded that the prescription had been accurately filled with tramadol. Presbitero did not directly inspect the amber vial or its contents. Had she done so, she would have seen that the amber vial contained 30 tablets of escitalopram.

15. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists, including Presbitero and Spears, to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients.

16. On information and belief, it became standard operating procedure for the pharmacists employed by CVS #6717 to use the accuracy scan technology as a substitute for a

direct visual inspection of the drugs that they dispensed to their patients. CVS #6717 actively encouraged adherence to this standard operating procedure.

17. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists to use the accuracy scan technology as a means of meeting production goals that would not otherwise have been met if pharmacists had performed a direct visual inspection of the drugs that they dispensed.

18. On January 4, 2024, CVS #6717 dispensed prescription no. 122493.

19. On or about January 31, 2024, patient J.F. called and returned to CVS #6717 carrying 19 tablets of tramadol in a plastic bag. Patient J.F. explained that she had received the wrong medication, and after an internal investigation, CVS #6717 confirmed that it had dispensed tramadol to patient J.F. instead of escitalopram, as prescribed.

20. Patient J.F. ingested eight tramadol tablets before she noticed the error and experienced drowsiness and hallucinations.

21. On January 5, 2024, CVS #6717 dispensed prescription no. 1223500. Patient T.B. picked up the prescription and immediately returned to the pharmacy because she noticed that she had only received 30 tablets instead of 90.

22. Although patient T.B. promptly returned to the pharmacy to complain about the tablet count, patient T.B. failed to notice that the tablets were escitalopram, not tramadol as prescribed.

23. Spears was the pharmacist on duty on January 5, 2024, when patient T.B. returned to the pharmacy to correct her tablet count. A pharmaceutical technician on duty at the time poured the 30 tablets into the pill counter and notified Spears of the 60-tablet shortage. Spears did not view the bottle or tablets. Another technician added 60 tablets of tramadol to the machine. All 90 tablets were then placed back into the amber vial and the technician handed it back to patient T.B.

24. After the patient had left the pharmacy, Spears viewed the original product image of the tablets associated with prescription no. 1223500. The image showed that patient T.B.'s prescription contained 90 tablets of tramadol, as opposed to the 30 tablets of escitalopram and 60 tablets of tramadol that were ultimately dispensed to her. Spears did not document the shortage, and he did not perform any further investigation.

25. Patient T.B. ingested all the medication in the amber vial for prescription no. 1223500.

26. Patient T.B. reported feeling more pain than usual, weight gain, and migraines.

27. On information and belief, patient T.B. ingested at least 30 tablets of the escitalopram that had been prescribed for patient J.F.

APPLICABLE LAW

28. Unprofessional conduct includes the failure by a registrant to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d).

29. Unprofessional conduct also includes a registrant or licensee performing duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

30. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702. Such a pharmacist must verify, among other things, the selection and strength of the drug, the dosage form, and the labeling of the prescription. NAC 639.252(2).

31. A pharmaceutical technician may perform one or more of the functions necessary to prepare a prescription only if the supervising pharmacist inspects the final product. NAC 639.245(2).

32. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Presbitero)

33. Presbitero engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she performed final verifications for prescription no. 1223493 and prescription no. 1223500 and failed to observe that the tablets in each of the amber vials did not correlate with the labels on each of the amber vials.

34. Having performed her duties in incompetent, unskillful, or negligent manner, as described above, Presbitero is subject to discipline pursuant to NRS 639.210(4).

COUNT TWO

Unprofessional Conduct – Error in Dispensing Prescription

(Respondent Spears)

35. Spears engaged in unprofessional conduct, as defined in NAC 639.945(1)(d) and (i), when he failed to perceive and correct the error in prescription no. 1223500 after patient T.B. returned with a complaint about the tablet count.

36. Although patient T.B. ultimately left the pharmacy with 90 tablets, including 60 tablets of tramadol, patient T.B. remained unaware that 30 of those tablets were never prescribed for her.

37. After becoming aware of the patient's complaint about the tablet count, Spears delegated to a pharmaceutical technician the responsibility to investigate and correct the discrepancy. Had Spears visually inspected the tablets, as opposed to a product image of the

tablets, he would have seen that the amber vial contained escitalopram instead of tramadol as indicated on the label.

38. Furthermore, Spears engaged in unprofessional conduct, as defined in NAC 639.945(1)(i), when he failed to investigate why patient T.B. received 30 tablets instead of 90 as prescribed.

39. Having performed his duties in incompetent, unskillful, or negligent manner, as described above, Spears is subject to discipline pursuant to NRS 639.210(4).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent CVS #6717)

40. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Respondent CVS #6717 is responsible for those violations, including all errors and omissions of Respondents Presbitero, Spears, and any other pharmacy personnel in the course of erroneously filling and dispensing prescription no. 1223493 and prescription no. 1223500.

41. Due to the unprofessional conduct of Presbitero, Spears, and/or other of its employees, CVS #6717 is subject to professional discipline pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

COUNT FOUR
Performing Duties in a Negligent Manner
(Respondent CVS #6717)

42. As alleged above, CVS #6717, acting through its corporate officers and managers, directed its pharmacists, including Presbitero and Spears, to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients.

43. As alleged above, it became standard operating procedure for the pharmacists employed by CVS #6717 to use the accuracy scan technology as a substitute for a direct visual inspection of the drugs that they dispensed to their patients. CVS #6717 actively encouraged adherence to this standard operating procedure.

44. On information and belief, CVS #6717, acting through its corporate officers and managers, directed its pharmacists to use the accuracy scan technology as a means of meeting production goals that would not otherwise have been met if pharmacists had performed a direct visual inspection of the drugs that they dispensed.

45. Pursuant to NAC 639.245 and NAC 639.252, CVS #6717 had a duty to ensure that its pharmacists performed a direct visual inspection of the drugs that they dispensed.

46. Acting through its officers and managers, CVS #6717 fostered a work environment in which its pharmacists were actively discouraged from performing a direct visual inspection of the drugs that they dispensed.

47. In light of the foregoing, CVS #6717 performed its duties as a licensee in an incompetent, unskillful, or negligent manner.

48. Due to its unprofessional conduct as alleged above, CVS #6717 caused prescription no. 1223493 and prescription no. 1223500 to be erroneously filled.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificates of registration of these Respondents.

Signed this 11th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TODD SPEARS, RPH,** **Certificate of Registration No. 18123,** **Respondent.**	**Case No. 24-013-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 3, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy, for and on behalf of
J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TODD SPEARS, RPH,** **Certificate of Registration No. 18123,** **Respondent.**	**Case No. 24-013-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Todd Spears, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

Analeah Presbitero, RPh
[redacted]
Las Vegas, NV [redacted]

Todd Spears, RPh
[redacted]
Henderson, NV [redacted]

Todd Spears, RPh
[redacted]
Henderson, NV [redacted]

Todd Spears, RPh
c/o CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

CVS Pharmacy #6717
c/o Brian J. Convery, Esq.
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895

Analeah Presbitero, RPh
c/o CVS Pharmacy #6717
60 N Valle Verde Dr
Henderson, NV 89074

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #6717,** **Pharmacy License No. PH01932,** **ANALEAH PRESBITERO, RPH,** **Certificate of Registration No. 23353, and** **TODD SPEARS, RPH,** **Certificate of Registration No. 18123,** **Respondents.**	**Case No.** **24-013-PH-S** **24-013-RPH-A-S** **24-013-RPH-B-S** **STIPULATION AND ORDER** **[TODD SPEARS ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Todd Spears, RPH, Certificate of Registration No. 18123, ("Respondent"), by and through counsel, Roger N. Morris, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The Board and Respondent agreed to delay the date for submitting a Notice of Answer and Defense as the parties pursued settlement negotiations.

4. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that he has executed it knowingly and voluntarily.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter

233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count Two of the Accusation, *to wit*:

A. On January 3, 2024, a pharmaceutical technician at CVS Pharmacy #6717 concurrently prepared prescription no. 1223493 for escitalopram and prescription no. 1223500 for tramadol.

B. According to the pharmaceutical technician, at some point after the pharmaceutical technician first handled prescription nos. 1223493 and 1223500, the label for the escitalopram was mistakenly affixed to the amber vial containing tramadol, and the label for the tramadol was mistakenly affixed to the amber vial containing escitalopram.

C. The pharmaceutical technician used the CVS virtual verification process and technology when preparing the above prescriptions.

D. On January 5, 2024, CVS Pharmacy #6717 dispensed prescription no. 1223500. Patient T.B. picked up the prescription and immediately returned to the pharmacy because she noticed that she had only received 30 tablets instead of 90.

E. Respondent was the pharmacist on duty on January 5, 2024, when patient T.B. returned to the pharmacy to correct her tablet count. A pharmaceutical technician on duty at the time poured the 30 tablets into the pill counter and notified Respondent of the 60-tablet shortage. Another technician added 60 tablets of tramadol to the

machine. All 90 tablets were then placed back into the amber vial and the technician handed it back to patient T.B.

F. After the patient had left the pharmacy, Respondent viewed the original product image of the tablets associated with prescription no. 1223500. The image showed that patient T.B.'s prescription contained 90 tablets of tramadol, as opposed to the 30 tablets of escitalopram and 60 tablets of tramadol that were likely dispensed to her. Respondent did not document the shortage, and he did not perform any further investigation.

G. Patient T.B. reported to have ingested all the medication in the amber vial for prescription no. 1223500.

H. Respondent failed to perceive and correct the error in prescription no. 1223500 after patient T.B. returned with a complaint about the tablet count.

8. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **One Thousand and 00/100 Dollars ($1,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

9. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-013-RPH-B-S. However, Respondent understands and acknowledges that his failure to comply with

the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

10. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

11. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____ 2026.

_____
TODD SPEARS, RPH
Certificate of Registration No. 18123

Signed this ____ day of _____ 2026.
Nevada State Board of Pharmacy

By_____
LAURA M. TUCKER, ESQ.
General Counsel

Approved as to Form and Content:

_____
ROGER N. MORRIS, ESQ.

Attorney for Respondent Todd Spears, RPH

DECISION AND ORDER

As to Todd Spears, in Case No. 24-013-RPH-B-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of March 2026.

_____
Helen Park, President
Nevada State Board of Pharmacy

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FILED
JUN 09 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA,** **Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Michael J. Stellmacher, PA ("Respondent") held a registration issued by the Board, Certificate of Registration No. CS21884.

FACTUAL ALLEGATIONS

2. At all times relevant to this accusation, Respondent has been employed as the medical director of Premier Beauty, LLC, also known as Channel Pro, (Premier Beauty), located at 4555 S. Fort Apache Road, Suite 104, in Las Vegas, Nevada.

3. Since at least December 28, 2023 until present, Joseph Gillis ("Gillis") owned and/or operated Premier Beauty. Since at least May 9, 2024 until present, Betty Dare ("Dare") was listed as the director of Premier Beauty. Gillis and Dare are not Nevada-licensed practitioners as that term is defined in NRS 639.0125 and NRS 453.126.

4. A Board investigation on August 29, 2024 revealed that Respondent permitted Gillis and Dare to have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondent's presence without Respondent's supervision.

5. Respondent admitted that he was the medical director of Premier Beauty, but that he rarely was on site and stated that he had no patient records. Respondent was not physically on-site at Premier Beauty while Board investigators were there.

6. Respondent permitted Dare to independently access, possess, furnish, and administer dangerous drugs to patients, to provide on-site medical treatment, including the administration of dangerous drugs through injection, specifically tirzepatide, semaglutide powders, and nicotinamide adenine dinucleotide (NAD), without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

7. Furthermore, the investigation revealed that these dangerous drugs were purchased from OUISA Pharmacy Corp. (OUISA), located in Spring Hill, Florida; OUISA not licensed as a wholesaler by the Board. The dangerous drugs were labeled as not for patient use.

8. Respondent permitted Gillis to purchase the drug products using the National Provider Identifier (NPI) number of Dr. Jayendrakumar Amin (Amin) and had the products shipped to California. Amin is located in California and does not hold any license or registration with the Board.

9. Premier Beauty's inventory included multiple vials of various injectable drugs intended for distribution in foreign markets and not approved for distribution or use in the United States, including medytox and other forms of botulinum toxins, multivitamin injections, and glutathione injections.

10. In at least one instance, Respondent's failure to supervise Dare while she administered tirzepatide to a patient resulted in patient harm. On June 7, 2024, Dare injected patient D.S. with tirzepatide and gave D.S. three more shots to take home with her. D.S. went to the emergency room with injuries from the injection. Respondent was not on site during the injection.

11. On or about February 19, 2025, the Board issued a cease-and-desist order with a citation and fine against Premier Beauty, Gillis, and Dare for unlicensed activity. On or about February 25, 2025, the Board issued a cease-and-desist order with a citation and fine against Amin for unlicensed wholesale activity.

APPLICABLE LAW

12. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213; NRS 454.217; NRS 454.221; NRS 454.316; NRS 454.321; NRS 454.356; NRS 639.100(1); NRS 639.1373.

13. Only those individuals permitted to do so pursuant to NRS 454.213 may possess, store, or administer dangerous drugs. Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

14. A physician assistant who is authorized to prescribe and dispense controlled substances and dangerous drugs may do so only for a legitimate medical purpose. NAC 639.280(1)(a).

15. All controlled substances and dangerous drugs in the possession of physician assistant must be kept in a locked storage area with access restricted to authorized persons. NAC 639.285(1).

16. The Board may suspend or revoke the certificate of registration of physician assistant that has failed to maintain the security of his or her drug supply. NAC 639.295(13).

17. It is unlawful to purchase, possess, sell, furnish or administer any drug product intended for distribution in foreign markets and not approved for distribution or use in the United States. 21 U.S.C. § 331; 21 U.S.C. § 355(a); NRS 454.351(1); NRS 585.490.

18. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of registration issued by the Board to a physician assistant. NRS 639.210(11); NAC 639.295(10).

19. The Board may revoke or suspend the registration of any physician assistant who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454, 585 or 639 of NRS or any regulation pertaining thereto. NRS 639.210(12) NAC 639.295(16).

20. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.295(4).

21. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.295(4).

22. It is unlawful for a physician assistant to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

23. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct contrary to the public pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.295(4).

24. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

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COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

25. By permitting Gillis and Dare to have unrestricted access to his inventory of dangerous drugs at Premier Beauty as alleged in paragraphs 4-5 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.285(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.295(13) and (16) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law – Unlawful Possession & Administration of Dangerous Drugs

26. By permitting an unlicensed individual to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed not determined that a dangerous drug was medically necessary, as alleged in paragraph 6 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 639.100(1) and/or NRS 639.1373, and is subject to discipline pursuant to NAC 639.295(16 and/or NRS 639.210(12).

COUNT THREE

Violations of Federal and State Law – Using Drugs Not Approved in the United States

27. By purchasing, possessing, selling, furnishing and/or administering drug products intended for distribution in foreign markets and not approved for distribution or use in the U.S., as alleged in paragraph 9 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 355(a), NRS 454.351(1) and/or NRS 585.490, and is subject to discipline pursuant to NAC 639.295(10) and/or NRS 639.210(11).

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COUNT FOUR

Unprofessional Conduct – Unlawful Possession & Administration of Dangerous Drugs

28. By his conduct as alleged in paragraphs 4-10 herein, Respondent performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and is subject to discipline pursuant to NAC 639.295(4) and/or NRS 639.210(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with Public Interest

29. By his conduct as alleged in paragraphs 4-10 herein, Respondent has committed acts that render registration inconsistent with public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to Respondent's Certificate of Registration No. CS21884.

Signed this 9th day of JUNE 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA,** **Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, July 16, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** L.Tucker@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of June 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA,** **Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Michael J. Stellmacher, PA

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of June 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Michael Stellmacher, PA
[redacted]
Fallon, NV [redacted]

Michael Stellmacher, PA
[redacted]
Pahrump, NV [redacted]

Michael Stellmacher, PA
[redacted]
Las Vegas, NV [redacted]

Forte Family Practice
c/o Michael Stellmacher, PA
9010 West Cheyenne Ave
Las Vegas, NV 89129

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL J. STELLMACHER, PA,** **Certificate of Registration No. CS21884,** **Respondent.**	**Case No. 24-364-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its General Counsel, Laura M. Tucker, and Respondent Michael J. Stellmacher, PA. ("Respondent"), by and through his counsel, Anthony Cortez, hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and he has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 453, the Nevada Controlled Substances Act, and NRS Chapter 639, the Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this

Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent does not contest the allegations stated in Count One, Count Two, Count Three, Count Four, and Count Five of the Accusation, and further admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged therein, to wit:

A. Respondent, a physician assistant, served as the medical director for Premier Beauty, LLC, also known as Channel Pro, (Premier Beauty), a medical spa located at 4555 S. Fort Apache Road, Suite 104, in Las Vegas, Nevada.

B. During Respondent's tenure as medical director, Respondent rarely visited the spa's location at 4555 S. Fort Apache Road, Suite 104.

C. During Respondent's tenure as medical director, Premier Beauty's owner and/or employees stored and possessed dangerous drugs at times when Respondent was not physically present at the spa's location at 4555 S. Fort Apache Road, Suite 104.

D. During Respondent's tenure as the medical director, a Premier Beauty employee administered injectable prescription drugs at times when Respondent was not physically present at the spa's location at 4555 S. Fort Apache Road, Suite 104, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

E. During Respondent's tenure as medical director, Premier Beauty's owner and/or employees ordered and received dangerous drugs labeled as not for patient use from OUISA Pharmacy Corp., located in Spring Hill, Florida, a wholesaler not licensed to engage in wholesale distribution in Nevada.

F. During Respondent's tenure as medical director, Premier Beauty's inventory included multiple vials of various injectable drugs intended for distribution in foreign markets and not approved for distribution or use in the United States, including medytox and other forms of botulinum toxins, multivitamin injections, and glutathione injections.

7. Now, therefore, to resolve the allegations stated in Count One, Count Two, Count Three, Count Four, and Count Five of the Accusation without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent accepts this Stipulation as a public reprimand.

B. Respondent agrees to pay an administrative fine of **Two Thousand Five Hundred and 00/100 Dollars ($2,500.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before April 30, 2026.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this case. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before April 30, 2026.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-364-CS-S. Any failure by Respondent to comply with the terms of this Stipulation may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing him to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in the finding of noncompliance by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639 and/or NRS Chapter 453.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear at the meeting.

10. The Board may accept this Stipulation, but it has no obligation to accept this Stipulation. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and

shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hold a contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the date of entry set forth below.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of ____ 2026.

_____
MICHAEL STELLMACHER, PA
Certificate of Registration No. CS21884

Signed this ____ day of _____ 2026.

NEVADA STATE BOARD OF PHARMACY

By_____
LAURA M. TUCKER, ESQ.
General Counsel

Approved as to Form and Content:

_____
ANTHONY CORTEZ, ESQ.

Attorney for Respondent Michael Stellmacher, PA

DECISION AND ORDER

As to Respondent Michael Stellmacher, PA, in Case No. 24-364-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and orders that its terms and conditions be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this __ day of March 2026.

_____
Helen Park, President
Nevada State Board of Pharmacy

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395, and** **NICOLE SY, RPH, Certificate of Registration No. 20646, and** **KIRK BEAULIEU, RPH, Certificate of Registration No. 20184,** **Respondents.**	**Case No. 25-110-PH-S** **25-110-RPH-A-S** **25-110-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, First Choice Pharmacy, LLC (First Choice) held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, and Respondent Nicole Sy, RPh (Sy), Certificate of Registration No. 20646, and Respondent Kirk Beaulieu, RPh (Beaulieu), Certificate of Registration No. 20184, were pharmacists registered with the Board.

FACTUAL ALLEGATIONS

2. Respondent First Choice, located at 7260 S. Cimmaron Road, Suite 115, in Las Vegas, Nevada, has been licensed by the Board under License No. PH04395 to operate as a pharmacy from June 6, 2022 through the present.

3. Respondent Sy was employed by First Choice as managing pharmacist from November 17, 2022 until October 27, 2023.

4. Respondent Beaulieu was employed by First Choice as managing pharmacist from December 1, 2023 through the present.

5. Rxeed is a wholesaling platform that represents itself on its website, www.rxeed.com, as an online marketplace that solicits and brokers the sales of prescription drug products between pharmacies across the United States.

6. Rxeed is not licensed to engage in business as a wholesaler in Nevada.

7. On or about April 10, 2024, during its annual inspection of First Choice, a Board Inspector found supplier invoices and shipping confirmations from Rxeed that demonstrated Rxeed was brokering sales from pharmacies in other states to First Choice in Nevada.

8. On or about October 10, 2024, the Board served an Order to Cease-and-Desist/Citation and Fine upon Rxeed for unlicensed wholesale distribution in Nevada. Rxeed satisfied the citation on June 12, 2025.

9. A Board investigation found that, between January 2023 and April 2024, through Rxeed, First Choice purchased drugs and/or prescription medical devices from twenty-three (23) pharmacies[1] that were not licensed with the Board to engage in wholesaling in Nevada.

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[1] The unlicensed pharmacies include Bayside Chemists/VUA Pharmacy; Care Express Pharmacy; Cypress Rx Inc; EZ Max Pharmacy; EZRX; Galaxy Pharmacy; Health Source RX; Lin Pharmacy; MDRX Pharmacy, Inc.; Med Need Rx Pharmacy LLC; Midtown Medicine; Niger Pharmacy and/or Patient Care Pharmacy; Ocean Pharmacy; Pharmacy 45; Planet Rx; Prime Plus Lakeview; Rapid Rx Inc; Red Ribbon Pharmacy Inc; SkyRx Pharmacy Inc.; Spectra Pharmacy Inc.; Sutphin Neighborhood Pharmacy; Town Rx, Inc; and VS Pharmacy Corp.

APPLICABLE LAW

10. Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license from the Board. NRS 639.233(1).

11. A pharmacist has a duty to exercise reasonable care when purchasing drugs from a wholesaler for resale to the public. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

12. The managing pharmacist of a pharmacy has a duty to acquire pharmacy stock from a lawful source and maintain the records of the stock as required by law. NAC 639.510. Furthermore, a managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(11), (12) and (15), and/or NRS 639.220(1).

13. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-l) establishes the requirements that certain entities in the pharmaceutical distribution supply chain, including pharmacies, must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

14. Every wholesale distributor who engages in wholesale distribution of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

15. Pursuant to Nevada law, exceptions involving pharmacy-to-pharmacy sales apply only in specific circumstances. NRS 639.0155.

16. Performing any duties as the owner of a business or entity licensed by the Board in an incompetent, unskillful, or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

17. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license by the Board. NRS 639.230(5). Furthermore, any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

18. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

19. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

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COUNT ONE

Unprofessional Conduct -Performing Duties in an Incompetent, Unskillful, or Negligent Manner

(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

20. As alleged above, between January 2023 and April 2024, First Choice purchased prescription drugs from twenty-three (23) pharmacies not licensed for wholesale distribution in Nevada through Rxeed.

21. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

22. Respondent Sy was employed by First Choice as managing pharmacist during the relevant time period until October 27, 2023.

23. Respondent Beaulieu was employed by First Choice as managing pharmacist during the relevant time period starting from December 1, 2023.

24. As a licensee of the Board, First Choice is responsible for the acts of all personnel in its employ.

25. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

26. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

27. Before engaging in the purchase of drugs from Rxeed in January 2023, First Choice and Sy had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. When Beaulieu assumed the position of managing pharmacist on December 1, 2023, he had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. NRS 639.210(11), (12) and (15), and/or NRS 639.220(1).

28. By failing to verify that Rxeed was a licensed wholesaler in Nevada, Respondents First Choice, Sy, and Beulieu performed their duties as a purchaser and as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner.

29. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions, Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

30. Respondents' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT TWO

Aiding or Abetting Violation of a State Law or Regulation
(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

31. Between January 2023 and April 2024, through Rxeed, Respondent purchased drugs from twenty-three pharmacies that were not licensed to engage in the business of wholesaling in Nevada.

32. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

33. Respondent Sy was employed by First Choice as managing pharmacist during the relevant time period until October 27, 2023.

34. Respondent Beaulieu was employed by First Choice as managing pharmacist during the relevant time period starting from December 1, 2023.

35. As a licensee of the Board, First Choice is responsible for the acts of all personnel in its employ.

36. Before engaging in the purchase of drugs from Rxeed in January 2023, Respondents had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233.

37. Upon the drugs' delivery, First Choice dispensed the drugs to patients in Nevada.

38. Respondents knew or should have known that Rxeed was not licensed by the Board to engage in the business of wholesale distribution in Nevada.

39. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

40. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

41. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions, Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

42. By dispensing drugs with actual or constructive knowledge of Rxeed's unlicensed activity as alleged above, Respondents permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling.

43. Respondent's conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(j).

COUNT THREE

Aiding or Abetting Violation of a Federal Law or Regulation
(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

44. Between January 2023 and April 2024, through Rxeed, Respondents purchased drugs from twenty-three pharmacies that were not licensed to engage in the business of wholesaling in Nevada.

45. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

46. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

47. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

48. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions,

Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

49. By purchasing products through Rxeed, a company not licensed to engage in the business of wholesale distribution in Nevada, Respondents permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling in violation of 21 U.S.C. § 360eee-l, 21 U.S.C. § 33l(t), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205.

50. Respondents' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(11).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 29th day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC,** **Pharmacy License No. PH04395,** **Respondent.**	**Case No. 25-110-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395,** **Respondent.**	**Case No. 25-110-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR
First Choice Pharmacy, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of October 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

First Choice Pharmacy
7260 S Cimarron Rd, Suite 115
Las Vegas, NV 89113

Nicole Sy, RPh
[redacted]
Las Vegas, NV [redacted]

American Wellness Pharmacy
c/o Nicole Sy, RPh
2775 S Jones Blvd, Suite 100A
Las Vegas, NV 89146

Kirk Beaulieu, RPh
[redacted]
Las Vegas, NV [redacted]

First Choice Pharmacy
c/o Kirk Beaulieu, RPh
7260 S Cimarron Rd, Suite 115
Las Vegas, NV 89113

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

Case No. 25-110-PH-S
25-110-RPH-A-S
25-110-RPH-B-S

V.

FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395, and NICOLE SY, RPH, Certificate of Registration No. 20646, and KIRK BEAULIEU, RPH, Certificate of Registration No. 20184,
Respondents.

ANSWER AND NOTICE OF DEFENSE:

Respondents First Choice Pharmacy, LLC, Kirk Beaulieu, RPh, and Nicole Sy, RPh, hereby submit this Answer and Notice of Defense to the *Notice of Intended Action and Accusation* filed by the Nevada State Board of Pharmacy ("Board"), and respectfully states as follows:

I. PRELIMINARY STATEMENT

1. Respondents deny each and every material allegation contained in the Notice of Intended Action and Accusation, except as expressly admitted herein.
2. Respondent Beaulieu has been a licensed pharmacist for thirty-five (35) years, maintaining licenses in Maine, New Hampshire, and Nevada without any prior disciplinary action.
3. Respondent Beaulieu has consistently conducted himself with integrity, diligence, and transparency in the practice of pharmacy, including during his employment with First Choice Pharmacy beginning December 1, 2023, where he served as Pharmacist-in-Charge ("PIC").
4. The transactions involving Rxeed referenced in the Board's allegations were pre-existing pharmacy practices that began prior to Respondent's employment. Respondents had no prior knowledge or notice that Rxeed was not licensed as a wholesaler in Nevada, and no directive or written communication from the Board, the pharmacy owners, or Rxeed indicated such status.
5. Respondents acted in good faith reliance on the pharmacy's established suppliers and on the Board's prior "good inspection" findings for the facility. At no time did he intend to violate any state or federal law or regulation.

II. RESPONSES TO SPECIFIC COUNTS

COUNT I – Unprofessional Conduct: Performing Duties in an Incompetent, Unskillful, or Negligent Manner

6. Respondents deny the allegations contained in Count I.
7. Respondent Beaulieu did not act incompetently, unskillfully, or negligently. He followed all known compliance practices and relied on prior Board inspections indicating that First Choice Pharmacy operated lawfully.
8. Upon the Board's subsequent notification that Rxeed was an unlicensed marketplace, Respondents immediately ceased all transactions with Rxeed and implemented procedures to verify all current and future wholesalers through the Nevada Board of Pharmacy's licensure database.
9. Respondents have since maintained full compliance and received a "good inspection" on February 11, 2025, from Board Inspector John Castaldo.

COUNT II – Aiding or Abetting Violation of State Law or Regulation

10. Respondents deny the allegations contained in Count II.
11. Respondents did not knowingly or intentionally aid, abet, or assist Rxeed in any unlawful activity. Rxeed the company presented itself as a licensed wholesaler with valid credentials.
12. Respondents had no constructive or actual knowledge of any unlicensed activity until receiving direct instruction from the Board in April 2024, at which point First Choice acted promptly to discontinue all Rxeed use and to verify compliance with NRS 639.239 and NAC 639.510.

COUNT III – Aiding or Abetting Violation of Federal Law or Regulation

13. Respondents deny the allegations contained in Count III.
14. Respondents did not engage in, or knowingly assist, any conduct that violated 21 U.S.C. §§ 331(t), 353(e)(2)(A), or 21 C.F.R. 205.4.
15. Respondents' actions were limited to lawful pharmacy practice in Nevada and in reliance on vendor representations and past inspections that indicated no regulatory issues.

III. MITIGATION AND CORRECTIVE ACTION

16. Respondents respectfully requests that the Board consider their full cooperation with Inspector Leo Basch during the April 5, 2024, inspection, where they provided all invoices and allowed inspection of Rxeed-sourced medications without hesitation or concealment.
17. At no time did Inspector Basch instruct Respondents to cease using Rxeed or indicate that it was unlicensed. The subsequent "good inspection" report further reinforced Respondents' reasonable belief in compliance.
18. Once the Board clarified Rxeed's unlicensed status, Respondents implemented the following corrective measures:

- Verified the licensure of every wholesaler currently doing business with the pharmacy;
- Instituted an internal verification SOP for vendor licensing checks;
- Educated pharmacy staff regarding Nevada wholesaler licensing requirements; and

- Documented all vendor license verifications for future Board inspection review.

19. Respondents have fully cooperated with all Board inquiries and has continued to maintain a compliant and transparent pharmacy operation since the event.

IV. CONCLUSION AND REQUEST FOR RELIEF

20. Respondents respectfully asserts that they acted in good faith, without intent to mislead or violate any law or regulation and corrected any compliance issue immediately upon notice.
21. Respondent Beaulieu's thirty-five-year record of professional service without prior discipline demonstrates his ongoing commitment to the safety and welfare of Nevada patients.
22. Respondents respectfully request that the Board dismiss all counts, or in the alternative, impose no disciplinary action in light of his cooperation, corrective action, and unblemished professional record.

V. VERIFICATION

Filed in a limited, unbundled capacity by Christopher L. Blakesley, Esq., on behalf of Respondents.

Dated this 02 day of December, 2025.



Christopher L. Blakesley, Esq.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395, and** **NICOLE SY, RPH, Certificate of Registration No. 20646, and** **KIRK BEAULIEU, RPH, Certificate of Registration No. 20184,** **Respondents.**	**Case No. 25-110-PH-S** **25-110-RPH-A-S** **25-110-RPH-B-S** **STIPULATION AND ORDER [FIRST CHOICE PHARMACY ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Respondent First Choice Pharmacy (Respondent), by and through counsel, Christopher L. Blakesley, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that it understands the terms of this Stipulation and Proposed Order ("Stipulation"), and it has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives its right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One, Count Two, and Count Three of the Accusation, to wit:

A. Between January 2023 and April 2024, Respondent purchased prescription drugs from twenty-three (23) pharmacies not licensed for wholesale distribution in Nevada through Rxeed, a wholesaling platform that is not licensed to engage in business as a wholesale in Nevada.

B. Before engaging in the purchase of drugs from Rxeed in January 2023, Respondent had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. By failing to verify that Rxeed was a licensed wholesaler in Nevada, Respondent performed its duties as a purchaser and as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner. *See* NRS 639.210(4); NAC 639.945(1)(i).

C. By dispensing drugs with actual or constructive knowledge of Rxeed's unlicensed activity, Respondent permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling, thereby engaging in unprofessional conduct. *See* NRS 639.210(4); NAC 639.945(1)(j).

D. By purchasing products through Rxeed, a company not licensed to engage in the business of wholesale distribution in Nevada, Respondent permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling in violation of 21 U.S.C. § 360eee-l, 21 U.S.C. § 33l(t), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205, thereby engaging in unprofessional conduct. *See* NRS 639.210(11).

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent accepts the Stipulation as a public reprimand imposed pursuant to NRS 639.255(1)(e).

B. Respondent shall pay an administrative fine of **Five Thousand and 00/100 Dollars ($5,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondents shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation and Order.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation and Order.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 25-110-PH-S. However, Respondent understands and acknowledges that its failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____ 2025.

FIRST CHOICE PHARMACY

By_____
Name:
Certificate of Registration No. PH04395

Signed this ____ day of _____ 2025.

_____
LAURA M. TUCKER, ESQ.
General Counsel
Nevada State Board of Pharmacy

Approved as to Form and Content:

_____
CHRISTOPHER L. BLAKESLEY, ESQ.
Attorney for Respondent

DECISION AND ORDER

As to First Choice Pharmacy, LLC, License No. PH04395, in Case No. 25-110-PH-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matters and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of March 2026.

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Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395, and** **NICOLE SY, RPH, Certificate of Registration No. 20646, and** **KIRK BEAULIEU, RPH, Certificate of Registration No. 20184,** **Respondents.**	**Case No. 25-110-PH-S** **25-110-RPH-A-S** **25-110-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, First Choice Pharmacy, LLC (First Choice) held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, and Respondent Nicole Sy, RPh (Sy), Certificate of Registration No. 20646, and Respondent Kirk Beaulieu, RPh (Beaulieu), Certificate of Registration No. 20184, were pharmacists registered with the Board.

FACTUAL ALLEGATIONS

2. Respondent First Choice, located at 7260 S. Cimmaron Road, Suite 115, in Las Vegas, Nevada, has been licensed by the Board under License No. PH04395 to operate as a pharmacy from June 6, 2022 through the present.

3. Respondent Sy was employed by First Choice as managing pharmacist from November 17, 2022 until October 27, 2023.

4. Respondent Beaulieu was employed by First Choice as managing pharmacist from December 1, 2023 through the present.

5. Rxeed is a wholesaling platform that represents itself on its website, www.rxeed.com, as an online marketplace that solicits and brokers the sales of prescription drug products between pharmacies across the United States.

6. Rxeed is not licensed to engage in business as a wholesaler in Nevada.

7. On or about April 10, 2024, during its annual inspection of First Choice, a Board Inspector found supplier invoices and shipping confirmations from Rxeed that demonstrated Rxeed was brokering sales from pharmacies in other states to First Choice in Nevada.

8. On or about October 10, 2024, the Board served an Order to Cease-and-Desist/Citation and Fine upon Rxeed for unlicensed wholesale distribution in Nevada. Rxeed satisfied the citation on June 12, 2025.

9. A Board investigation found that, between January 2023 and April 2024, through Rxeed, First Choice purchased drugs and/or prescription medical devices from twenty-three (23) pharmacies[1] that were not licensed with the Board to engage in wholesaling in Nevada.

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[1] The unlicensed pharmacies include Bayside Chemists/VUA Pharmacy; Care Express Pharmacy; Cypress Rx Inc; EZ Max Pharmacy; EZRX; Galaxy Pharmacy; Health Source RX; Lin Pharmacy; MDRX Pharmacy, Inc.; Med Need Rx Pharmacy LLC; Midtown Medicine; Niger Pharmacy and/or Patient Care Pharmacy; Ocean Pharmacy; Pharmacy 45; Planet Rx; Prime Plus Lakeview; Rapid Rx Inc; Red Ribbon Pharmacy Inc; SkyRx Pharmacy Inc.; Spectra Pharmacy Inc.; Sutphin Neighborhood Pharmacy; Town Rx, Inc; and VS Pharmacy Corp.

APPLICABLE LAW

10. Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license from the Board. NRS 639.233(1).

11. A pharmacist has a duty to exercise reasonable care when purchasing drugs from a wholesaler for resale to the public. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

12. The managing pharmacist of a pharmacy has a duty to acquire pharmacy stock from a lawful source and maintain the records of the stock as required by law. NAC 639.510. Furthermore, a managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(11), (12) and (15), and/or NRS 639.220(1).

13. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-l) establishes the requirements that certain entities in the pharmaceutical distribution supply chain, including pharmacies, must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

14. Every wholesale distributor who engages in wholesale distribution of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

15. Pursuant to Nevada law, exceptions involving pharmacy-to-pharmacy sales apply only in specific circumstances. NRS 639.0155.

16. Performing any duties as the owner of a business or entity licensed by the Board in an incompetent, unskillful, or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

17. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license by the Board. NRS 639.230(5). Furthermore, any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

18. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

19. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

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COUNT ONE

Unprofessional Conduct -Performing Duties in an Incompetent, Unskillful, or Negligent Manner

(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

20. As alleged above, between January 2023 and April 2024, First Choice purchased prescription drugs from twenty-three (23) pharmacies not licensed for wholesale distribution in Nevada through Rxeed.

21. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

22. Respondent Sy was employed by First Choice as managing pharmacist during the relevant time period until October 27, 2023.

23. Respondent Beaulieu was employed by First Choice as managing pharmacist during the relevant time period starting from December 1, 2023.

24. As a licensee of the Board, First Choice is responsible for the acts of all personnel in its employ.

25. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

26. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

27. Before engaging in the purchase of drugs from Rxeed in January 2023, First Choice and Sy had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. When Beaulieu assumed the position of managing pharmacist on December 1, 2023, he had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. NRS 639.210(11), (12) and (15), and/or NRS 639.220(1).

28. By failing to verify that Rxeed was a licensed wholesaler in Nevada, Respondents First Choice, Sy, and Beulieu performed their duties as a purchaser and as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner.

29. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions, Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

30. Respondents' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT TWO

Aiding or Abetting Violation of a State Law or Regulation
(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

31. Between January 2023 and April 2024, through Rxeed, Respondent purchased drugs from twenty-three pharmacies that were not licensed to engage in the business of wholesaling in Nevada.

32. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

33. Respondent Sy was employed by First Choice as managing pharmacist during the relevant time period until October 27, 2023.

34. Respondent Beaulieu was employed by First Choice as managing pharmacist during the relevant time period starting from December 1, 2023.

35. As a licensee of the Board, First Choice is responsible for the acts of all personnel in its employ.

36. Before engaging in the purchase of drugs from Rxeed in January 2023, Respondents had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233.

37. Upon the drugs' delivery, First Choice dispensed the drugs to patients in Nevada.

38. Respondents knew or should have known that Rxeed was not licensed by the Board to engage in the business of wholesale distribution in Nevada.

39. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

40. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

41. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions, Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

42. By dispensing drugs with actual or constructive knowledge of Rxeed's unlicensed activity as alleged above, Respondents permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling.

43. Respondent's conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(j).

COUNT THREE

Aiding or Abetting Violation of a Federal Law or Regulation
(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

44. Between January 2023 and April 2024, through Rxeed, Respondents purchased drugs from twenty-three pharmacies that were not licensed to engage in the business of wholesaling in Nevada.

45. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

46. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

47. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

48. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions,

Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

49. By purchasing products through Rxeed, a company not licensed to engage in the business of wholesale distribution in Nevada, Respondents permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling in violation of 21 U.S.C. § 360eee-l, 21 U.S.C. § 33l(t), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205.

50. Respondents' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(11).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 23rd day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NICOLE SY, RPH,** **Certificate of Registration No. 20646,** **Respondent.**	**Case No. 25-110-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NICOLE SY, RPH,** **Certificate of Registration No. 20646,** **Respondent.**	**Case No. 25-110-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Nicole Sy, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of October 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

First Choice Pharmacy
7260 S Cimarron Rd, Suite 115
Las Vegas, NV 89113

Nicole Sy, RPh
[redacted]
Las Vegas, NV [redacted]

American Wellness Pharmacy
c/o Nicole Sy, RPh
2775 S Jones Blvd, Suite 100A
Las Vegas, NV 89146

Kirk Beaulieu, RPh
[redacted]
Las Vegas, NV [redacted]

First Choice Pharmacy
c/o Kirk Beaulieu, RPh
7260 S Cimarron Rd, Suite 115
Las Vegas, NV 89113

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

Case No. 25-110-PH-S
25-110-RPH-A-S
25-110-RPH-B-S

V.

FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395, and NICOLE SY, RPH, Certificate of Registration No. 20646, and KIRK BEAULIEU, RPH, Certificate of Registration No. 20184,
Respondents.

ANSWER AND NOTICE OF DEFENSE:

Respondents First Choice Pharmacy, LLC, Kirk Beaulieu, RPh, and Nicole Sy, RPh, hereby submit this Answer and Notice of Defense to the *Notice of Intended Action and Accusation* filed by the Nevada State Board of Pharmacy ("Board"), and respectfully states as follows:

I. PRELIMINARY STATEMENT

1. Respondents deny each and every material allegation contained in the Notice of Intended Action and Accusation, except as expressly admitted herein.
2. Respondent Beaulieu has been a licensed pharmacist for thirty-five (35) years, maintaining licenses in Maine, New Hampshire, and Nevada without any prior disciplinary action.
3. Respondent Beaulieu has consistently conducted himself with integrity, diligence, and transparency in the practice of pharmacy, including during his employment with First Choice Pharmacy beginning December 1, 2023, where he served as Pharmacist-in-Charge ("PIC").
4. The transactions involving Rxeed referenced in the Board's allegations were pre-existing pharmacy practices that began prior to Respondent's employment. Respondents had no prior knowledge or notice that Rxeed was not licensed as a wholesaler in Nevada, and no directive or written communication from the Board, the pharmacy owners, or Rxeed indicated such status.
5. Respondents acted in good faith reliance on the pharmacy's established suppliers and on the Board's prior "good inspection" findings for the facility. At no time did he intend to violate any state or federal law or regulation.

II. RESPONSES TO SPECIFIC COUNTS

COUNT I – Unprofessional Conduct: Performing Duties in an Incompetent, Unskillful, or Negligent Manner

6. Respondents deny the allegations contained in Count I.
7. Respondent Beaulieu did not act incompetently, unskillfully, or negligently. He followed all known compliance practices and relied on prior Board inspections indicating that First Choice Pharmacy operated lawfully.
8. Upon the Board's subsequent notification that Rxeed was an unlicensed marketplace, Respondents immediately ceased all transactions with Rxeed and implemented procedures to verify all current and future wholesalers through the Nevada Board of Pharmacy's licensure database.
9. Respondents have since maintained full compliance and received a "good inspection" on February 11, 2025, from Board Inspector John Castaldo.

COUNT II – Aiding or Abetting Violation of State Law or Regulation

10. Respondents deny the allegations contained in Count II.
11. Respondents did not knowingly or intentionally aid, abet, or assist Rxeed in any unlawful activity. Rxeed the company presented itself as a licensed wholesaler with valid credentials.
12. Respondents had no constructive or actual knowledge of any unlicensed activity until receiving direct instruction from the Board in April 2024, at which point First Choice acted promptly to discontinue all Rxeed use and to verify compliance with NRS 639.239 and NAC 639.510.

COUNT III – Aiding or Abetting Violation of Federal Law or Regulation

13. Respondents deny the allegations contained in Count III.
14. Respondents did not engage in, or knowingly assist, any conduct that violated 21 U.S.C. §§ 331(t), 353(e)(2)(A), or 21 C.F.R. 205.4.
15. Respondents' actions were limited to lawful pharmacy practice in Nevada and in reliance on vendor representations and past inspections that indicated no regulatory issues.

III. MITIGATION AND CORRECTIVE ACTION

16. Respondents respectfully requests that the Board consider their full cooperation with Inspector Leo Basch during the April 5, 2024, inspection, where they provided all invoices and allowed inspection of Rxeed-sourced medications without hesitation or concealment.
17. At no time did Inspector Basch instruct Respondents to cease using Rxeed or indicate that it was unlicensed. The subsequent "good inspection" report further reinforced Respondents' reasonable belief in compliance.
18. Once the Board clarified Rxeed's unlicensed status, Respondents implemented the following corrective measures:

    - Verified the licensure of every wholesaler currently doing business with the pharmacy;
    - Instituted an internal verification SOP for vendor licensing checks;
    - Educated pharmacy staff regarding Nevada wholesaler licensing requirements; and

- Documented all vendor license verifications for future Board inspection review.

19. Respondents have fully cooperated with all Board inquiries and has continued to maintain a compliant and transparent pharmacy operation since the event.

IV. CONCLUSION AND REQUEST FOR RELIEF

20. Respondents respectfully asserts that they acted in good faith, without intent to mislead or violate any law or regulation and corrected any compliance issue immediately upon notice.
21. Respondent Beaulieu's thirty-five-year record of professional service without prior discipline demonstrates his ongoing commitment to the safety and welfare of Nevada patients.
22. Respondents respectfully request that the Board dismiss all counts, or in the alternative, impose no disciplinary action in light of his cooperation, corrective action, and unblemished professional record.

V. VERIFICATION

Filed in a limited, unbundled capacity by Christopher L. Blakesley, Esq., on behalf of Respondents.

Dated this 02 day of December, 2025.



Christopher L. Blakesley, Esq.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC,** **Pharmacy License No. PH04395, and** **NICOLE SY, RPH,** **Certificate of Registration No. 20646, and** **KIRK BEAULIEU, RPH,** **Certificate of Registration No. 20184,** **Respondents.**	**Case No. 25-110-PH-S** **25-110-RPH-A-S** **25-110-RPH-B-S** **STIPULATION AND ORDER** **[NICOLE SY, RPH ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Respondent Nicole Sy, Certificate of Registration No. 20646, (Respondent), by and through counsel, Christopher L. Blakesley, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that she understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that she has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One, Count Two, and Count Three of the Accusation, to wit:

A. Between January 2023 and October 2023, while employed as managing pharmacist at First Choice Pharmacy (First Choice), Respondent purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada through Rxeed, a wholesaling platform that is not licensed to engage in business as a wholesale in Nevada.

B. Before engaging in the purchase of drugs through Rxeed, had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. By failing to verify that Rxeed was a licensed wholesaler in Nevada, Respondent performed her duties as a managing pharmacist of the purchaser and as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner. *See* NRS 639.210(4); NAC 639.945(1)(i).

C. By dispensing drugs with actual or constructive knowledge of Rxeed's unlicensed activity, Respondent permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling, thereby engaging in unprofessional conduct. *See* NRS 639.210(4); NAC 639.945(1)(j).

D. By purchasing products through Rxeed, a company not licensed to engage in the business of wholesale distribution in Nevada, Respondent permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling in violation of 21 U.S.C. § 360eee-l, 21 U.S.C. § 33l(t), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205, thereby engaging in unprofessional conduct. *See* NRS 639.210(11).

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent accepts the Stipulation as a public reprimand imposed pursuant to NRS 639.255(1)(e).

B. Respondent shall pay an administrative fine of **Five Thousand and 00/100 Dollars ($5,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by July 1, 2026.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by July 1, 2026.

D. Respondent shall complete two (2) hours of continuing education (CE) on ethics and two (2) hours of CE on duties of a managing pharmacist, in addition to the CE hours she must otherwise complete to maintain licensure, and shall provide certificates demonstrating completion of the additional CEs by July 1, 2026.

8. This Stipulation constitutes a full and final resolution of the Accusation in 25-110-RPH-A-S. However, Respondent understands and acknowledges that her failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las

Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____ 2026.

NICOLE SY, RPH
Certificate of Registration No. 20646

Signed this ____ day of _____ 2026.

LAURA M. TUCKER, ESQ.
General Counsel
Nevada State Board of Pharmacy

Approved as to Form and Content:

CHRISTOPHER L. BLAKESLEY, ESQ.
Attorney for Respondent

DECISION AND ORDER

As to Respondent Nicole Sy, Certificate of Registration No. 20646, in Case No. 25-110-RPH-A-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matters and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of March 2026.

_____

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395, and** **NICOLE SY, RPH, Certificate of Registration No. 20646, and** **KIRK BEAULIEU, RPH, Certificate of Registration No. 20184,** **Respondents.**	**Case No. 25-110-PH-S** **25-110-RPH-A-S** **25-110-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, First Choice Pharmacy, LLC (First Choice) held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, and Respondent Nicole Sy, RPh (Sy), Certificate of Registration No. 20646, and Respondent Kirk Beaulieu, RPh (Beaulieu), Certificate of Registration No. 20184, were pharmacists registered with the Board.

FACTUAL ALLEGATIONS

2. Respondent First Choice, located at 7260 S. Cimmaron Road, Suite 115, in Las Vegas, Nevada, has been licensed by the Board under License No. PH04395 to operate as a pharmacy from June 6, 2022 through the present.

3. Respondent Sy was employed by First Choice as managing pharmacist from November 17, 2022 until October 27, 2023.

4. Respondent Beaulieu was employed by First Choice as managing pharmacist from December 1, 2023 through the present.

5. Rxeed is a wholesaling platform that represents itself on its website, www.rxeed.com, as an online marketplace that solicits and brokers the sales of prescription drug products between pharmacies across the United States.

6. Rxeed is not licensed to engage in business as a wholesaler in Nevada.

7. On or about April 10, 2024, during its annual inspection of First Choice, a Board Inspector found supplier invoices and shipping confirmations from Rxeed that demonstrated Rxeed was brokering sales from pharmacies in other states to First Choice in Nevada.

8. On or about October 10, 2024, the Board served an Order to Cease-and-Desist/Citation and Fine upon Rxeed for unlicensed wholesale distribution in Nevada. Rxeed satisfied the citation on June 12, 2025.

9. A Board investigation found that, between January 2023 and April 2024, through Rxeed, First Choice purchased drugs and/or prescription medical devices from twenty-three (23) pharmacies[1] that were not licensed with the Board to engage in wholesaling in Nevada.

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[1] The unlicensed pharmacies include Bayside Chemists/VUA Pharmacy; Care Express Pharmacy; Cypress Rx Inc; EZ Max Pharmacy; EZRX; Galaxy Pharmacy; Health Source RX; Lin Pharmacy; MDRX Pharmacy, Inc.; Med Need Rx Pharmacy LLC; Midtown Medicine; Niger Pharmacy and/or Patient Care Pharmacy; Ocean Pharmacy; Pharmacy 45; Planet Rx; Prime Plus Lakeview; Rapid Rx Inc; Red Ribbon Pharmacy Inc; SkyRx Pharmacy Inc.; Spectra Pharmacy Inc.; Sutphin Neighborhood Pharmacy; Town Rx, Inc; and VS Pharmacy Corp.

APPLICABLE LAW

10. Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license from the Board. NRS 639.233(1).

11. A pharmacist has a duty to exercise reasonable care when purchasing drugs from a wholesaler for resale to the public. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

12. The managing pharmacist of a pharmacy has a duty to acquire pharmacy stock from a lawful source and maintain the records of the stock as required by law. NAC 639.510. Furthermore, a managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(11), (12) and (15), and/or NRS 639.220(1).

13. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-l) establishes the requirements that certain entities in the pharmaceutical distribution supply chain, including pharmacies, must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

14. Every wholesale distributor who engages in wholesale distribution of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

15. Pursuant to Nevada law, exceptions involving pharmacy-to-pharmacy sales apply only in specific circumstances. NRS 639.0155.

16. Performing any duties as the owner of a business or entity licensed by the Board in an incompetent, unskillful, or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

17. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license by the Board. NRS 639.230(5). Furthermore, any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

18. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

19. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

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COUNT ONE

Unprofessional Conduct -Performing Duties in an Incompetent, Unskillful, or Negligent Manner

(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

20. As alleged above, between January 2023 and April 2024, First Choice purchased prescription drugs from twenty-three (23) pharmacies not licensed for wholesale distribution in Nevada through Rxeed.

21. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

22. Respondent Sy was employed by First Choice as managing pharmacist during the relevant time period until October 27, 2023.

23. Respondent Beaulieu was employed by First Choice as managing pharmacist during the relevant time period starting from December 1, 2023.

24. As a licensee of the Board, First Choice is responsible for the acts of all personnel in its employ.

25. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

26. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

27. Before engaging in the purchase of drugs from Rxeed in January 2023, First Choice and Sy had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. When Beaulieu assumed the position of managing pharmacist on December 1, 2023, he had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. NRS 639.210(11), (12) and (15), and/or NRS 639.220(1).

28. By failing to verify that Rxeed was a licensed wholesaler in Nevada, Respondents First Choice, Sy, and Beulieu performed their duties as a purchaser and as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner.

29. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions, Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

30. Respondents' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT TWO

Aiding or Abetting Violation of a State Law or Regulation
(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

31. Between January 2023 and April 2024, through Rxeed, Respondent purchased drugs from twenty-three pharmacies that were not licensed to engage in the business of wholesaling in Nevada.

32. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

33. Respondent Sy was employed by First Choice as managing pharmacist during the relevant time period until October 27, 2023.

34. Respondent Beaulieu was employed by First Choice as managing pharmacist during the relevant time period starting from December 1, 2023.

35. As a licensee of the Board, First Choice is responsible for the acts of all personnel in its employ.

36. Before engaging in the purchase of drugs from Rxeed in January 2023, Respondents had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233.

37. Upon the drugs' delivery, First Choice dispensed the drugs to patients in Nevada.

38. Respondents knew or should have known that Rxeed was not licensed by the Board to engage in the business of wholesale distribution in Nevada.

39. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

40. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

41. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions, Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

42. By dispensing drugs with actual or constructive knowledge of Rxeed's unlicensed activity as alleged above, Respondents permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling.

43. Respondent's conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(j).

COUNT THREE

Aiding or Abetting Violation of a Federal Law or Regulation
(Respondents First Choice Pharmacy, Respondent Sy, and Respondent Beaulieu)

44. Between January 2023 and April 2024, through Rxeed, Respondents purchased drugs from twenty-three pharmacies that were not licensed to engage in the business of wholesaling in Nevada.

45. During the relevant time period, Rxeed did not hold a license with the Board to engage in the business of wholesale distribution in Nevada.

46. Rxeed had a legal obligation to obtain a wholesaler license based upon its role as a broker for the sales.

47. Each of the pharmacies selling to First Choice had a legal obligation to obtain a wholesaler license based upon its role as seller.

48. Based upon the facts and circumstances surrounding the transactions, including the existence of documentary proof that Rxeed was brokering *pharmacy-to-pharmacy* transactions,

Respondents had duty to inquire as to whether Rxeed and/or each of the pharmacies was licensed to engage in wholesale distribution.

49. By purchasing products through Rxeed, a company not licensed to engage in the business of wholesale distribution in Nevada, Respondents permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling in violation of 21 U.S.C. § 360eee-l, 21 U.S.C. § 33l(t), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205.

50. Respondents' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(11).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 23rd day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KIRK BEAULIEU, RPH,** **Certificate of Registration No. 20184,** **Respondent.**	**Case No. 25-110-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KIRK BEAULIEU, RPH,** **Certificate of Registration No. 20184,** **Respondent.**	**Case No. 25-110-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Kirk Beaulieu, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of October 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

First Choice Pharmacy
7260 S Cimarron Rd, Suite 115
Las Vegas, NV 89113

Nicole Sy, RPh
[redacted]
Las Vegas, NV [redacted]

American Wellness Pharmacy
c/o Nicole Sy, RPh
2775 S Jones Blvd, Suite 100A
Las Vegas, NV 89146

Kirk Beaulieu, RPh
[redacted]
Las Vegas, NV [redacted]

First Choice Pharmacy
c/o Kirk Beaulieu, RPh
7260 S Cimarron Rd, Suite 115
Las Vegas, NV 89113

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD OF PHARMACY,

Petitioner,

Case No. 25-110-PH-S
25-110-RPH-A-S
25-110-RPH-B-S

V.

FIRST CHOICE PHARMACY, LLC, Pharmacy License No. PH04395, and NICOLE SY, RPH, Certificate of Registration No. 20646, and KIRK BEAULIEU, RPH, Certificate of Registration No. 20184,
Respondents.

ANSWER AND NOTICE OF DEFENSE:

Respondents First Choice Pharmacy, LLC, Kirk Beaulieu, RPh, and Nicole Sy, RPh, hereby submit this Answer and Notice of Defense to the *Notice of Intended Action and Accusation* filed by the Nevada State Board of Pharmacy ("Board"), and respectfully states as follows:

I. PRELIMINARY STATEMENT

1. Respondents deny each and every material allegation contained in the Notice of Intended Action and Accusation, except as expressly admitted herein.
2. Respondent Beaulieu has been a licensed pharmacist for thirty-five (35) years, maintaining licenses in Maine, New Hampshire, and Nevada without any prior disciplinary action.
3. Respondent Beaulieu has consistently conducted himself with integrity, diligence, and transparency in the practice of pharmacy, including during his employment with First Choice Pharmacy beginning December 1, 2023, where he served as Pharmacist-in-Charge ("PIC").
4. The transactions involving Rxeed referenced in the Board's allegations were pre-existing pharmacy practices that began prior to Respondent's employment. Respondents had no prior knowledge or notice that Rxeed was not licensed as a wholesaler in Nevada, and no directive or written communication from the Board, the pharmacy owners, or Rxeed indicated such status.
5. Respondents acted in good faith reliance on the pharmacy's established suppliers and on the Board's prior "good inspection" findings for the facility. At no time did he intend to violate any state or federal law or regulation.

II. RESPONSES TO SPECIFIC COUNTS

COUNT I – Unprofessional Conduct: Performing Duties in an Incompetent, Unskillful, or Negligent Manner

6. Respondents deny the allegations contained in Count I.
7. Respondent Beaulieu did not act incompetently, unskillfully, or negligently. He followed all known compliance practices and relied on prior Board inspections indicating that First Choice Pharmacy operated lawfully.
8. Upon the Board's subsequent notification that Rxeed was an unlicensed marketplace, Respondents immediately ceased all transactions with Rxeed and implemented procedures to verify all current and future wholesalers through the Nevada Board of Pharmacy's licensure database.
9. Respondents have since maintained full compliance and received a "good inspection" on February 11, 2025, from Board Inspector John Castaldo.

COUNT II – Aiding or Abetting Violation of State Law or Regulation

10. Respondents deny the allegations contained in Count II.
11. Respondents did not knowingly or intentionally aid, abet, or assist Rxeed in any unlawful activity. Rxeed the company presented itself as a licensed wholesaler with valid credentials.
12. Respondents had no constructive or actual knowledge of any unlicensed activity until receiving direct instruction from the Board in April 2024, at which point First Choice acted promptly to discontinue all Rxeed use and to verify compliance with NRS 639.239 and NAC 639.510.

COUNT III – Aiding or Abetting Violation of Federal Law or Regulation

13. Respondents deny the allegations contained in Count III.
14. Respondents did not engage in, or knowingly assist, any conduct that violated 21 U.S.C. §§ 331(t), 353(e)(2)(A), or 21 C.F.R. 205.4.
15. Respondents' actions were limited to lawful pharmacy practice in Nevada and in reliance on vendor representations and past inspections that indicated no regulatory issues.

III. MITIGATION AND CORRECTIVE ACTION

16. Respondents respectfully requests that the Board consider their full cooperation with Inspector Leo Basch during the April 5, 2024, inspection, where they provided all invoices and allowed inspection of Rxeed-sourced medications without hesitation or concealment.
17. At no time did Inspector Basch instruct Respondents to cease using Rxeed or indicate that it was unlicensed. The subsequent "good inspection" report further reinforced Respondents' reasonable belief in compliance.
18. Once the Board clarified Rxeed's unlicensed status, Respondents implemented the following corrective measures:

    - Verified the licensure of every wholesaler currently doing business with the pharmacy;
    - Instituted an internal verification SOP for vendor licensing checks;
    - Educated pharmacy staff regarding Nevada wholesaler licensing requirements; and

- Documented all vendor license verifications for future Board inspection review.

19. Respondents have fully cooperated with all Board inquiries and has continued to maintain a compliant and transparent pharmacy operation since the event.

IV. CONCLUSION AND REQUEST FOR RELIEF

20. Respondents respectfully asserts that they acted in good faith, without intent to mislead or violate any law or regulation and corrected any compliance issue immediately upon notice.
21. Respondent Beaulieu's thirty-five-year record of professional service without prior discipline demonstrates his ongoing commitment to the safety and welfare of Nevada patients.
22. Respondents respectfully request that the Board dismiss all counts, or in the alternative, impose no disciplinary action in light of his cooperation, corrective action, and unblemished professional record.

V. VERIFICATION

Filed in a limited, unbundled capacity by Christopher L. Blakesley, Esq., on behalf of Respondents.

Dated this 02 day of December, 2025.



Christopher L. Blakesley, Esq.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FIRST CHOICE PHARMACY, LLC,** **Pharmacy License No. PH04395, and** **NICOLE SY, RPH,** **Certificate of Registration No. 20646, and** **KIRK BEAULIEU, RPH,** **Certificate of Registration No. 20184,** **Respondents.**	**Case No. 25-110-PH-S** **25-110-RPH-A-S** **25-110-RPH-B-S** **STIPULATION AND ORDER** **[KIRK BEAULIEU, RPH ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Respondent Kirk Beulieu, Certificate of Registration No. 20184, (Respondent), by and through counsel, Christopher L. Blakesley, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that he has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One, Count Two, and Count Three of the Accusation, to wit:

A. Between December 2023 and April 2024, while employed as managing pharmacist at First Choice Pharmacy (First Choice), Respondent purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada through Rxeed, a wholesaling platform that is not licensed to engage in business as a wholesale in Nevada.

B. Before engaging in the purchase of drugs through Rxeed, Respondent had a duty to request proof that Rxeed was a licensed wholesaler in Nevada pursuant to NRS 639.233. By failing to verify that Rxeed was a licensed wholesaler in Nevada, Respondent performed his duties as a managing pharmacist of the purchaser and as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner. *See* NRS 639.210(4); NAC 639.945(1)(i).

C. By dispensing drugs with actual or constructive knowledge of Rxeed's unlicensed activity, Respondent permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling, thereby engaging in unprofessional conduct. *See* NRS 639.210(4); NAC 639.945(1)(j).

D. By purchasing products through Rxeed, a company not licensed to engage in the business of wholesale distribution in Nevada, Respondent permitted Rxeed to engage in, or assisted or abetted Rxeed in, the unlicensed practice of wholesaling in violation of 21 U.S.C. § 360eee-l, 21 U.S.C. § 33l(t), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205, thereby engaging in unprofessional conduct. *See* NRS 639.210(11).

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent accepts the Stipulation as a public reprimand imposed pursuant to NRS 639.255(1)(e).

B. Respondent shall pay an administrative fine of **Five Thousand and 00/100 Dollars ($5,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation and Order.

C. Respondent shall pay the sum of **One Thousand and 00/100 Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation and Order.

D. Respondent shall complete two (2) hours of continuing education (CE) on ethics and two (2) hours of CE on duties of a managing pharmacist, in addition to the CE hours he must otherwise complete to maintain licensure, and shall provide certificates demonstrating completion of the additional CEs by July 1, 2026.

8. This Stipulation constitutes a full and final resolution of the Accusation in 25-110-RPH-B-S. However, Respondent understands and acknowledges that his failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

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Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____ 2026.

KIRK BEAULIEU, RPH
Certificate of Registration No. 20184

Signed this ____ day of _____ 2026.

LAURA M. TUCKER, ESQ.
General Counsel
Nevada State Board of Pharmacy

Approved as to Form and Content:

CHRISTOPHER L. BLAKESLEY, ESQ.
Attorney for Respondent

DECISION AND ORDER

As to Respondent Kirk Beaulieu, Certificate of Registration No. 20184, in Case No. 25-110-RPH-A-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matters and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of March 2026.

_____

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JILL OLIVER, MD,** **Certificate of Registration Nos. CS15479 and PD15479,** **Respondent.**	**Case No. 25-111-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Jill Oliver, MD, (Respondent) held Certificate of Registration No. CS15479 issued by the Board, authorizing her to prescribe controlled substances, and Certificate of Registration No. PD15479 issued by the Board, authorizing her to dispense dangerous drugs and/or controlled substances.

FACTUAL ALLEGATIONS

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice medicine in Nevada.

3. At all times mentioned herein, Respondent was a "practitioner" as that term is defined at NRS 639.0125.

4. Since 2005, Respondent has held a certificate of registration issued by the Board pursuant to NRS 453.226, authorizing her to prescribe controlled substances, and has held a certificate of registration issued pursuant to NAC 639.742 authorizing her to dispense dangerous drugs and/or controlled substances.

5. Respondent is the owner/operator of Glimpse Medical Center - Anthem, located at 10170 S. Eastern Avenue #100, Henderson, NV 89052.

6. At all times relevant herein, medical assistant Trixie Ceballos (Ceballos) was employed at Glimpse Medical Center.

7. On or about March 6, 2025, Respondent submitted a dispensing technician license application for Ceballos with the supporting training documentation. The training documentation showed that Ceballos had completed 1,561 hours of training under Respondent's supervision.

8. According to Board records, Ceballos never obtained a dispensing technician in training license as required by NAC 639.7424.

9. From on or about June 20, 2023 until July 31 2024, Ceballos performed dispensing technician in training duties without an active dispensing technician in training license.

10. Respondent supervised and employed Ceballos during the timeframe that Ceballos performed dispensing technician in training duties without a license.

11. On September 10, 2021, the Board disciplined Respondent for allowing a dispensing technician to practice on an expired license for 115 days. The Board order Respondent to pay a fine of $5,000.

APPLICABLE LAW

12. A dispensing technician in training must hold a license with the Board and may not perform the duties of a dispensing technician in training without a license. NAC 639.7424.

13. A dispensing practitioner shall not allow any person to act as a dispensing technician in training without a license/registration. NAC 639.7424(6); NAC 639.7435; NAC 639.7445.

14. Performing any duties as the holder of a dispensing registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(l)(i) and is grounds for suspension or

revocation of any license or registration issued by the Board. NRS 639.210(4) and (12); NRS 639.255.

15. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(l)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NRS 639.255.

16. A business or facility owner is responsible for violations committed by its employees or personnel. NAC 639.945(2).

COUNT ONE

Unprofessional Conduct – Assisting or abetting unlicensed practice

17. As alleged above, Ceballos should have obtained a dispensing technician in training license prior to performing duties as a dispensing technician in training. NAC 639.7424.

18. As alleged above, Respondent allowed Ceballos to act a dispensing technician in training without the required license from on or about June 20, 2023 until July 31 2024 in violation of NAC 639.7424(6); NAC 639.7435; NAC 639.7445.

19. By allowing Ceballos to perform the duties of a dispensing technician in training without the required license, Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and (j).

20. This is a violation of law for which the Board may impose administrative discipline. *See* NRS 639.210(4), and (12), and/or NRS 639.255.

COUNT TWO

Owner Responsibilities

21. As the owner of Glimpse Medical Center at all times relevant to the above allegations, Respondent is responsible for all violations of law, including those of her employees, pursuant to NAC 639.945(2).

22. This is a violation of law for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12) and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Jill Oliver, MD.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JILL OLIVER, MD,** **Certificate of Registration Nos. CS15479 and PD15479,** **Respondent.**	**Case No. 25-111-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JILL OLIVER, MD,** **Certificate of Registration Nos. CS15479 and PD15479,** **Respondent.**	**Case No. 25-111-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

JILL OLIVER, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of January 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Jill Oliver, MD
[redacted]
Las Vegas, NV [redacted]

Jill Oliver, MD
10170 S. Eastern Ave. #100
Henderson, NV 89052

Jill Oliver, MD c/o
Glimpse Medical
5990 S. Rainbow Blvd. #100
Las Vegas, NV 89118

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JILL OLIVER, MD,** **Certificate of Registration Nos. CS15479 and PD15479,** **Respondent.**	**Case No. 25-111-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

Please see attached.

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

Please see attached.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

Jan 29, 2026

Jill Oliver M.D.
Jill Oliver M.D. (Jan 29, 2026 17:03:09 PST)

JILL OLIVER, MD

FILED
JAN 30 2026
NEVADA STATE BOARD OF PHARMACY

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Attorneys for Jill Oliver, M.D.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. JILL OLIVER, M.D. Certificates of Registration Nos. CS15479 and PD15479, Respondent.	CASE NO.: 25-111-CS-S **ANSWER AND NOTICE OF DEFENSE**

I. Objections to the Accusation

Respondent has no present objections to the Accusation as being incomplete or failing to state clearly the charges against her, but reserves the right to raise such objection(s) through the course of proceedings.

II. Answer to the Accusation

Respondent admits, denies, and alleges as follows:

A. With regard to Paragraphs 1 through 7, Respondent admits to the allegations contained therein

B. With regard to Paragraph 8, Respondent admits that Ceballos had not obtained a

dispensing technician in training ("TDT"[1]) license prior to March 6, 2025.

1. Respondent notes that the TDT license requirement (NAC 639.7424) became effective December 29, 2022, approximately six (6) months prior to the commencement of Ceballos's dispensing technician training as an employee of Glimpse of Vegas Inc., dba Glimpse Medical ("Glimpse Medical" or "Practice").

2. Respondent states that as a dispensing practitioner, she has trained three (3) dispensing technicians in her Practice between 2012 and 2020, long prior to the adoption of NAC 639.7424.

3. Respondent states that Practice staff contacted the Board for guidance on Ceballos's dispensing technician application ("TD Application") on several occasions prior to submitting the TD Application on or about March 6, 2025.

4. Respondent states that Practice staff were informed by the Board, in pertinent part, to leave the "TDT Registration #" blank on the TD Application, but were never informed of the TDT license requirement itself.

5. Respondent states she was unaware that that dispensing technician training requirements had changed, or that a TDT license was now required, until she was contacted by Ken Scheuber by telephone on or about March 21, 2025.

6. Respondent asserts that she then took immediate remedial action, by (a) submitting a TDT application for Ceballos on March 21, 2025, which was approved by the Board on March 27, 2025; and (b) by so far providing 1,376 hours of additional dispensing technician training for Ceballos as of January 23, 2026.

7. Respondent notes that when Ceballos again applies for a TD license, she will have had over 3,000 hours of dispensing technician training.

C. With regard to Paragraph 9, Respondent denies the allegations contained in that paragraph.

1. The duties of a dispensing technician, and thus a dispensing technician in training, include NAC 639.742(4):

(a) Entering the room or cabinet in which drugs are stored;

(b) Removing drugs from stock;

[1] The Board apparently refers to dispensing technicians as "TD" and dispensing technicians in training as "TDT".

(c) Counting, pouring or reconstituting drugs;

(d) Placing drugs into containers;

(e) Producing and affixing appropriate labels to containers that contain or will contain drugs;

(f) Filling containers for later use in dispensing drugs; or

(g) Packaging or repackaging drugs.

2. Respondent asserts that, from on or about June 20, 2023 until July 31, 2024 ("Training Period"):

(a) Ceballos did not enter any room where drugs were stored unless accompanied by Respondent and a dispensing technician duly licensed by the Board, and did not have access to any cabinets where drugs were stored;

(b) Ceballos did not remove any drugs from stock;

(c) Ceballos did not count, pour, or reconstitute any drugs;

(d) Ceballos did not place any drugs into containers;

(e) Ceballos did not produce or affix any labels to containers that did contain or would contain drugs;

(f) Ceballos did not fill any containers for later use in dispensing drugs; and

(g) Ceballos did not package or repackage any drugs.

3. Respondent states that Ceballos was employed by Glimpse Medical as a medical assistant, and was to continue working primarily as a medical assistant even after obtaining TD licensure, and was to serve as TD only in the unusual event no other TD of Glimpse Medical was available.

4. Respondent states that because Ceballos was not expected to actively function as a TD at the Practice, her training during the Training Period had been limited to use of the computer system and observation of the technical duties of the TD.

D. With regard to Paragraph 10, Respondent admits that Ceballos was an employee of Glimpse Medical and under Respondent's supervision during the Training Period, but denies the remaining allegations in this paragraph.

1. As stated above, Respondent provided Ceballos with education related to the duties of a TD, should she ever need to serve in that role once licensed.

2. As stated above, Respondent denies that Ceballos performed any of the

technical duties of a TD or TDT during the Training Period.

E. With regard to Paragraph 11, Respondent admits the allegations contained in this paragraph.

1. Respondent asserts that because of the 2021 disciplinary action by the Board, and on the advice of Board inspector Luis Curras during a January 23, 2020 inspection of Glimpse Medical, Respondent determined to train and obtain TD licenses for all Glimpse Medical employees, to ensure there would never again be a lapse in TD availability.

2. Respondent states that Ceballos was the only employee of Glimpse Medical who had not yet been trained and licensed as a TD.

F. Paragraphs 12 through 16 do not contain allegations against the Respondent. To the extent an answer is required, the Respondent denies the allegations in those paragraphs.[2]

G. With regard to Paragraph 17, Respondent admits that a TDT license is required pursuant to NAC 639.7424, but denies that Ceballos performed any technical duties of a TDT or a TD during the Training Period.

H. With regards to Paragraphs 18 through 20, Respondent denies the allegations contained in these paragraphs, and repeats paragraphs A through G above as if fully set forth herein.

I. With regard to Paragraph 21, Respondent admits that as the owner of Glimpse Medical she is responsible for the acts of all personnel in her employ, but denies that any of her employees have been found to have committed any violations of law related to the events set forth in the Notice.

J. With regard to Paragraph 22, Respondent denies the allegations contained in this paragraph, and repeats paragraphs A through I above as if fully set forth herein.

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[2] Paragraphs 16 and 21 of the Notice refer to NAC 639.945(2), which states "It is not unprofessional conduct or conduct contrary to the public interest for a practitioner to prescribe or dispense a drug under the circumstances described in paragraph (n) of subsection 1 if the drug is prescribed or dispensed in accordance with either publication adopted by reference in NAC 639.055." For the purposes of this Answer, Respondent assumes the intended reference is to NAC 639.945(3), which states, "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ," and responds to these paragraphs accordingly.

The undersigned hereby declares, under penalty of perjury, that the foregoing Answer and Notice of Defense and all facts therein stated, are true and correct to best of her knowledge.

Dated Jan 29, 2026.

Jill Oliver M.D.
Jill Oliver M.D. (Jan 29, 2026 17:03:09 PST)

Jill Oliver, M.D.

On behalf of Respondent:

NUTILE LAW

/s/ Bridget Kelly

Maria Nutile, Esq.
Nevada Bar No.: 7847
Bridget Kelly, Esq.
Nevada Bar No.: 14388
NUTILE LAW
7395 S. Pecos Rd., Suite 103
Las Vegas, Nevada 89120
Telephone: (702) 307-4880
Facsimile: (702) 307-4881
Email: maria@nutilelaw.com
bridget@nutilelaw.com

Answer and Notice of Defense 25-111-CS-S

Final Audit Report 2026-01-30

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By:	Bridget Kelly (Bridget@nutilelaw.com)
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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JILL OLIVER, MD,** **Certificate of Registration Nos. CS15479 and PD15479,** **Respondent.**	**Case No. 25-111-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Jill Oliver, MD, ("Respondent"), by and through counsel, Bridget Kelly, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that she understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that she has executed it knowingly and voluntarily.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded to Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in Count One and Count Two, *to wit*:

A. Respondent allowed an employee to perform duties as a dispensing technician in training without the required license as required by NAC 639.7424(6); NAC 639.7435; NAC 639.7445, thereby engaging in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and (j).

B. As owner of Glimpse Medical Center, Respondent is responsible for all violations of law, including those of her employees, pursuant to NAC 639.945(2). The Board may impose administrative discipline pursuant to NRS 639.210(4) and (12) and/or NRS 639.255

7. Now, therefore, to resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties. The certificate of registration nos. CS15479 and PD15479 shall be SUSPENDED; however, the suspension is STAYED, and Respondent shall be placed on probation pursuant to NRS 639.255(1)(b) for a period of one (1) year subject to the following conditions:

A. Respondent shall pay an administrative fine of **Two Thousand and 00/100 Dollars ($2,000.00)**, payable by *cashier's check, certified check,* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

B. Respondent shall pay the sum of **Five Hundred and 00/100 Dollars ($500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *cashier's check, certified check,* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

Upon successful completion of the terms and conditions of probation as forth herein, Respondent's certificates of registration shall be automatically reinstated without conditions or restrictions.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 25-111-CS-S. However, Respondent understands and acknowledges that her failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 4, 2026, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Feb 17, 2026

Signed this ____ day of _____ 2026.

Jill Oliver M.D.
Jill Oliver M.D. (Feb 17, 2026 15:39:29 PST)

JILL OLIVER, MD
Certificate of Registration Nos. CS15479 and PD15479

Signed this ____ day of _____ 2026.

NEVADA STATE BOARD OF PHARMACY

By_____
LAURA M. TUCKER, ESQ.
General Counsel

Approved as to Form and Content:

Bridget Kelly

BRIDGET KELLY, ESQ.
Attorney for Respondent Jill Oliver, MD

DECISION AND ORDER

As to Jill Oliver, in Case No. 25-111-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 4th day of March 2026.

Helen Park, President
Nevada State Board of Pharmacy

Case No. 25-111-CS-S Oliver Jill Stip, Resp. executed

Final Audit Report 2026-02-17

Created:	2026-02-17
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"Case No. 25-111-CS-S Oliver Jill Stip, Resp. executed" History

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561, and** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondents.**	**Case No. 25-360-PH-S** **25-360-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Lyfe Pharmacy, Inc. (Lyfe), License No. PH04561, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, and Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From February 5, 2024, through February 4, 2026, Lyfe, located at 9280 W. Sunset Road #230, in Las Vegas, held Pharmacy License No. PH04561 authorizing the operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Lyfe's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Lyfe.

4. On information and belief, dangerous drugs and controlled substances were received, stored, and dispensed at Lyfe Pharmacy between February 5, 2024, and September 26, 2024.

5. On or about September 26, 2024, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Lyfe to be sold to Ramy Massoud (Massoud) outside the jurisdiction of the Board. Massoud was not and is not currently licensed by the Board to operate a pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

6. Massoud took possession of Lyfe's assets on September 26, 2024, and he began to act at that time as the putative pharmacy owner in control of the premises at 9280 W. Sunset Road #230, in Las Vegas.

7. From September 26, 2024 until January 27, 2026, with putative owner Massoud having assumed control of the assets of the pharmacy, Massoud began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

8. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 9280 W. Sunset Road #230, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

9. From September 26, 2024 through February 4, 2026, putative owner Massoud continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Lyfe, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Lyfe with Massoud as the owner.

10. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Lyfe. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Lyfe was closed by the Board.

11. On or about February 4, 2026, the Board secured all drugs and medical records on Lyfe's premises. Lyfe's managing pharmacist volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

12. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

13. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

14. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

15. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

16. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the

provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

17. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

18. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

19. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Violation of State Regulation – Failure to Submit Change of Ownership
(Respondent Nigmatova)

20. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

21. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

22. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

23. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Permitting Unlicensed Practice
(Respondent Nigmatova)

24. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

25. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Massoud, the putative new owner of Lyfe, did not legally obtain licensure to

operate the pharmacy. As such, during the relevant time period, Massoud did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

26. As alleged above, during the relevant time period, Massoud, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

27. By failing to file an application for change of ownership for Lyfe and causing putative owner Massoud, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS 639.230(2), Nigmatova permitted Massoud to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

28. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent Lyfe Pharmacy)

29. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Lyfe is responsible for those violations, including all errors and omissions of Respondent Nigmatova and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Lyfe Pharmacy, Inc. and Nazakat Nigmatova, RPh.

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DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561, and** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent(s).**	**Case Nos. 25-360-PH-S** **25-360-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561,** **Respondent.**	**Case No. 25-360-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR LYFE PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Lyfe Pharmacy
9280 W Sunset Rd. #230
Las Vegas, NV 89148

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

LYFE PHARMACY,
Pharmacy License No. PH04561, and

NAZAKAT NIGMATOVA, RPH,
Certificate of Registration No. 20601,

Respondents.

Case No. 25-360-PH-S
25-360-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

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FACTUAL ALLEGATIONS

2. From February 5, 2024, through February 4, 2026, Lyfe, located at 9280 W. Sunset Road #230, in Las Vegas, held Pharmacy License No. PH04561 authorizing the operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Lyfe's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Lyfe.

4. On information and belief, dangerous drugs and controlled substances were received, stored, and dispensed at Lyfe Pharmacy between February 5, 2024, and September 26, 2024.

5. On or about September 26, 2024, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Lyfe to be sold to Ramy Massoud (Massoud) outside the jurisdiction of the Board. Massoud was not and is not currently licensed by the Board to operate a pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

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7. From September 26, 2024 until January 27, 2026, with putative owner Massoud having assumed control of the assets of the pharmacy, Massoud began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

8. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 9280 W. Sunset Road #230, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

9. From September 26, 2024 through February 4, 2026, putative owner Massoud continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Lyfe, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Lyfe with Massoud as the owner.

10. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Lyfe. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Lyfe was closed by the Board.

11. On or about February 4, 2026, the Board secured all drugs and medical records on Lyfe's premises. Lyfe's managing pharmacist volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

12. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

13. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

14. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

15. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

16. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the

provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

17. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

18. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

19. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Violation of State Regulation – Failure to Submit Change of Ownership
(Respondent Nigmatova)

20. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

21. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 9280 W. Sunset Road #230, in Las Vegas, Nevada.

22. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

23. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Permitting Unlicensed Practice
(Respondent Nigmatova)

24. As alleged above, on or about September 26, 2024, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Lyfe to be sold to Massoud.

25. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Massoud, the putative new owner of Lyfe, did not legally obtain licensure to

operate the pharmacy. As such, during the relevant time period, Massoud did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

26. As alleged above, during the relevant time period, Massoud, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

27. By failing to file an application for change of ownership for Lyfe and causing putative owner Massoud, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS 639.230(2), Nigmatova permitted Massoud to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

28. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent Lyfe Pharmacy)

29. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Lyfe is responsible for those violations, including all errors and omissions of Respondent Nigmatova and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Lyfe Pharmacy, Inc. and Nazakat Nigmatova, RPh.

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DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LYFE PHARMACY,** **Pharmacy License No. PH04561, and** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent(s).**	**Case Nos. 25-360-PH-S** **25-360-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent.**	**Case No. 25-360-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

NAZAKAT NIGMATOVA, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Nazokat Nigmatova, RPH
c/o Evergreen Pharmacy
4110 S Maryland Pkwy., Ste. 17
Las Vegas, NV 89119

Nazokat Nigmatova, RPH
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No. 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Tera Pharmacy (Tera), License No. PH04648, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board, and Respondent Grace Singson, RPh (Singson), Certificate of Registration No. 24727, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From November 21, 2024, through February 4, 2026, Tera, located at 8995 W. Flamingo Road, Suite 120, in Las Vegas, held Pharmacy License No. PH04648 authorizing the

operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Tera's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Tera. As stated in the application, Tera initially conducted business under the name Lyfe Pharmacy 2.

4. On or about December 2, 2024, Nigmatova filed an application with the Board to change the pharmacy's name from Lyfe Pharmacy 2 to Tera Pharmacy. The Board's staff approved the application.

5. On or about June 11, 2025, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to a buyer who is not licensed by the Board to operate a pharmacy.

6. On or about September 19, 2025 without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova again ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to Mark Mahfouz (Mahfouz), who was not and is not currently licensed by the Board to operate a pharmacy at 8995 W. Flamingo Road, Suite 120.

7. Mahfouz took possession of Tera's assets on September 19, 2025, and he began to act at that time as the putative pharmacy owner in control of the premises at 8995 W. Flamingo Road, Suite 120, in Las Vegas.

8. From September 19, 2025 until January 27, 2026, with putative owner Mahfouz having assumed control of the assets of the pharmacy, Mahfouz began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

9. On or about October 16, 2025, Singson notified the Board that she had become managing pharmacist at Tera.

10. On or about November 25, 2025, Board Inspector Leo Basch (Basch) performed an annual inspection of Tera. During the inspection, Basch noted several deficiencies, including:

a. From on or about October 29, 2025 to October 30, 2025, Singson processed at least seven (7) prescriptions for various controlled substances that did not have a quantity indicated on the prescription or a prescriber's signature;

b. On or about October 29, 2025, Singson processed at least one (1) prescription for a controlled substance that did not have the prescriber's signature;

c. On or about November 4, 2025, Singson accepted a transferred prescription for testosterone, a controlled substance, that was missing the days' supply, the address of the pharmacy the prescription was received from, the total number of refills, and the number of refills remaining; and

d. On or about October 22, 2025, a phoned-in prescription was written for multiple medications for one patient and was missing the initials of the pharmacist who took the call. When questioned, Singson stated that she took the prescription over the phone.

11. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

12. From September 19, 2025 through February 4, 2026, putative owner Mahfouz continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Tera, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Tera with Mahfouz as the owner.

13. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Tera. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Tera was closed by the Board.

14. On or about February 4, 2026, the Board secured all drugs and medical records on Tera's premises. On February 5, 2026, Singson volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

15. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

16. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

17. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

18. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

19. In Nevada, written prescriptions for controlled substances must contain, among other things, the name and signature of the practitioner and the name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled. NRS 639.2353(2). All filled prescriptions must be retained on file for at least two years, and each prescription on file must be personally signed or initialed by the registered pharmacist who filled it. NRS 639.236(2); NAC 639.751.

20. Only a registered pharmacist or a registered pharmaceutical intern acting under the direct supervision of a registered pharmacist may identify, evaluate, and interpret a prescription. NAC 639.700(2). Pharmacists are responsible for verifying prescriptions prepared by pharmaceutical technicians, including, but not limited to the selection and strength of the drug and the dosage form. NAC 639.252(2). Pharmacists also have discretion not to fill a prescription if the prescription does not meet certain standards. NAC 639.752.

21. Performing any duties as the holder of a license, certificate or registration issued by the Board in an incompetent, unskillful, or negligent manner is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(i).

22. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

23. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

25. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Violation of State Regulation – Failure to Submit Change of Ownership
(Respondent Nigmatova)

26. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

27. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada.

28. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

29. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Permitting Unlicensed Practice
(Respondent Nigmatova)

30. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

31. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Mahfouz, the putative new owner of Tera, did not legally obtain licensure to operate the pharmacy. As such, during the relevant time period, Mahfouz did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

32. As alleged above, during the relevant time period, Mahfouz, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

33. By failing to file an application for change of ownership for Tera and causing putative owner Mahfouz, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS

639.230(2), Nigmatova permitted Mahfouz to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

34. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Unprofessional Conduct – Performing Duties in a Negligent Manner
(Respondent Singson)

35. As alleged above, between October 22, 2025 to November 4, 2025, Singson, as managing pharmacist at Tera, processed at least ten (10) prescriptions with missing information that is required by Nevada law or regulation. NRS 639.2353(2); NRS 639.236(2); NAC 639.751.

36. As the registered pharmacist on duty, Singson had a duty to verify, evaluate and interpret the prescriptions received at Tera. NAC 639.700(2); NAC 639.252(2); NAC 639.752.

37. By filling prescriptions that were not valid under Nevada law, Signson performed her duties as a licensee in a negligent manner. NAC 639.945(1)(i).

38. Singson's conduct as alleged above amounts to unprofessional conduct as defined by NAC 639.945(1)(i); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4).

COUNT FOUR
Pharmacy/Pharmacy Owner Responsibility
(Respondent Tera Pharmacy)

39. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Tera is responsible for those violations, including all errors and omissions of Respondent Nigmatova and Respondent Singson and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Tera Pharmacy, Nazakat Nigmatova, RPh, and Grace Singson, RPh.

DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No(s). 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2)

copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **Respondent.**	**Case No. 25-370-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR TERA PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Tera Pharmacy
8995 W Flamingo Rd., Ste. 120
Las Vegas, NV 89147

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No. 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Tera Pharmacy (Tera), License No. PH04648, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board, and Respondent Grace Singson, RPh (Singson), Certificate of Registration No. 24727, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From November 21, 2024, through February 4, 2026, Tera, located at 8995 W. Flamingo Road, Suite 120, in Las Vegas, held Pharmacy License No. PH04648 authorizing the

operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Tera's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Tera. As stated in the application, Tera initially conducted business under the name Lyfe Pharmacy 2.

4. On or about December 2, 2024, Nigmatova filed an application with the Board to change the pharmacy's name from Lyfe Pharmacy 2 to Tera Pharmacy. The Board's staff approved the application.

5. On or about June 11, 2025, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to a buyer who is not licensed by the Board to operate a pharmacy.

6. On or about September 19, 2025 without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova again ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to Mark Mahfouz (Mahfouz), who was not and is not currently licensed by the Board to operate a pharmacy at 8995 W. Flamingo Road, Suite 120.

7. Mahfouz took possession of Tera's assets on September 19, 2025, and he began to act at that time as the putative pharmacy owner in control of the premises at 8995 W. Flamingo Road, Suite 120, in Las Vegas.

8. From September 19, 2025 until January 27, 2026, with putative owner Mahfouz having assumed control of the assets of the pharmacy, Mahfouz began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

9. On or about October 16, 2025, Singson notified the Board that she had become managing pharmacist at Tera.

10. On or about November 25, 2025, Board Inspector Leo Basch (Basch) performed an annual inspection of Tera. During the inspection, Basch noted several deficiencies, including:

a. From on or about October 29, 2025 to October 30, 2025, Singson processed at least seven (7) prescriptions for various controlled substances that did not have a quantity indicated on the prescription or a prescriber's signature;

b. On or about October 29, 2025, Singson processed at least one (1) prescription for a controlled substance that did not have the prescriber's signature;

c. On or about November 4, 2025, Singson accepted a transferred prescription for testosterone, a controlled substance, that was missing the days' supply, the address of the pharmacy the prescription was received from, the total number of refills, and the number of refills remaining; and

d. On or about October 22, 2025, a phoned-in prescription was written for multiple medications for one patient and was missing the initials of the pharmacist who took the call. When questioned, Singson stated that she took the prescription over the phone.

11. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

12. From September 19, 2025 through February 4, 2026, putative owner Mahfouz continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Tera, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Tera with Mahfouz as the owner.

13. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Tera. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Tera was closed by the Board.

14. On or about February 4, 2026, the Board secured all drugs and medical records on Tera's premises. On February 5, 2026, Singson volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

15. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

16. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

17. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

18. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

19. In Nevada, written prescriptions for controlled substances must contain, among other things, the name and signature of the practitioner and the name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled. NRS 639.2353(2). All filled prescriptions must be retained on file for at least two years, and each prescription on file must be personally signed or initialed by the registered pharmacist who filled it. NRS 639.236(2); NAC 639.751.

20. Only a registered pharmacist or a registered pharmaceutical intern acting under the direct supervision of a registered pharmacist may identify, evaluate, and interpret a prescription. NAC 639.700(2). Pharmacists are responsible for verifying prescriptions prepared by pharmaceutical technicians, including, but not limited to the selection and strength of the drug and the dosage form. NAC 639.252(2). Pharmacists also have discretion not to fill a prescription if the prescription does not meet certain standards. NAC 639.752.

21. Performing any duties as the holder of a license, certificate or registration issued by the Board in an incompetent, unskillful, or negligent manner is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(i).

22. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

23. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

25. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Violation of State Regulation – Failure to Submit Change of Ownership (Respondent Nigmatova)

26. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

27. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada.

28. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

29. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Permitting Unlicensed Practice (Respondent Nigmatova)

30. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

31. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Mahfouz, the putative new owner of Tera, did not legally obtain licensure to operate the pharmacy. As such, during the relevant time period, Mahfouz did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

32. As alleged above, during the relevant time period, Mahfouz, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

33. By failing to file an application for change of ownership for Tera and causing putative owner Mahfouz, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS

639.230(2), Nigmatova permitted Mahfouz to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

34. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Unprofessional Conduct – Performing Duties in a Negligent Manner
(Respondent Singson)

35. As alleged above, between October 22, 2025 to November 4, 2025, Singson, as managing pharmacist at Tera, processed at least ten (10) prescriptions with missing information that is required by Nevada law or regulation. NRS 639.2353(2); NRS 639.236(2); NAC 639.751.

36. As the registered pharmacist on duty, Singson had a duty to verify, evaluate and interpret the prescriptions received at Tera. NAC 639.700(2); NAC 639.252(2); NAC 639.752.

37. By filling prescriptions that were not valid under Nevada law, Signson performed her duties as a licensee in a negligent manner. NAC 639.945(1)(i).

38. Singson's conduct as alleged above amounts to unprofessional conduct as defined by NAC 639.945(1)(i); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4).

COUNT FOUR
Pharmacy/Pharmacy Owner Responsibility
(Respondent Tera Pharmacy)

39. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Tera is responsible for those violations, including all errors and omissions of Respondent Nigmatova and Respondent Singson and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Tera Pharmacy, Nazakat Nigmatova, RPh, and Grace Singson, RPh.

DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No(s). 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2)

copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601,** **Respondent.**	**Case No. 25-370-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

NAZAKAT NIGMATOVA, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Nazokat Nigmatova, RPH
c/o Evergreen Pharmacy
4110 S Maryland Pkwy., Ste. 17
Las Vegas, NV 89119

Nazokat Nigmatova, RPH
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No. 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Tera Pharmacy (Tera), License No. PH04648, held a license issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy, Respondent Nazakat Nigmatova, RPh (Nigmatova), Certificate of Registration No. 20601, was a pharmacist registered with the Board, and Respondent Grace Singson, RPh (Singson), Certificate of Registration No. 24727, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. From November 21, 2024, through February 4, 2026, Tera, located at 8995 W. Flamingo Road, Suite 120, in Las Vegas, held Pharmacy License No. PH04648 authorizing the

operation of a pharmacy in compliance with the terms of the new pharmacy application personally submitted by Nigmatova on Tera's behalf.

3. Respondent Nigmatova, a registered pharmacist, signed the initial application in her capacity as the president and 100% shareholder of Tera. As stated in the application, Tera initially conducted business under the name Lyfe Pharmacy 2.

4. On or about December 2, 2024, Nigmatova filed an application with the Board to change the pharmacy's name from Lyfe Pharmacy 2 to Tera Pharmacy. The Board's staff approved the application.

5. On or about June 11, 2025, without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to a buyer who is not licensed by the Board to operate a pharmacy.

6. On or about September 19, 2025 without giving prior notice to the Board pursuant to NAC 639.227, Nigmatova again ostensibly caused the assets of Tera to be sold outside the jurisdiction of the Board. The assets of Tera were ostensibly relinquished to Mark Mahfouz (Mahfouz), who was not and is not currently licensed by the Board to operate a pharmacy at 8995 W. Flamingo Road, Suite 120.

7. Mahfouz took possession of Tera's assets on September 19, 2025, and he began to act at that time as the putative pharmacy owner in control of the premises at 8995 W. Flamingo Road, Suite 120, in Las Vegas.

8. From September 19, 2025 until January 27, 2026, with putative owner Mahfouz having assumed control of the assets of the pharmacy, Mahfouz began, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell controlled substances.

9. On or about October 16, 2025, Singson notified the Board that she had become managing pharmacist at Tera.

10. On or about November 25, 2025, Board Inspector Leo Basch (Basch) performed an annual inspection of Tera. During the inspection, Basch noted several deficiencies, including:

a. From on or about October 29, 2025 to October 30, 2025, Singson processed at least seven (7) prescriptions for various controlled substances that did not have a quantity indicated on the prescription or a prescriber's signature;

b. On or about October 29, 2025, Singson processed at least one (1) prescription for a controlled substance that did not have the prescriber's signature;

c. On or about November 4, 2025, Singson accepted a transferred prescription for testosterone, a controlled substance, that was missing the days' supply, the address of the pharmacy the prescription was received from, the total number of refills, and the number of refills remaining; and

d. On or about October 22, 2025, a phoned-in prescription was written for multiple medications for one patient and was missing the initials of the pharmacist who took the call. When questioned, Singson stated that she took the prescription over the phone.

11. On or about January 27, 2026, the Board received notice that agents from the federal Drug Enforcement Administration (DEA) had seized the stock of controlled substances at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada. The DEA seized the controlled substances because no pharmacy owner was registered with the DEA at that location to prescribe or dispense controlled substances as required by federal law.

12. From September 19, 2025 through February 4, 2026, putative owner Mahfouz continued, on his own account and without the Board's knowledge or consent, to receive, possess, store, hold for sale, and/or sell dangerous drugs. During that time, Nigmatova did not act as pharmacy owner of Tera, and Nigmatova never submitted, and the Board had never approved, a change of ownership application for Tera with Mahfouz as the owner.

13. On or about February 4, 2026, following a Board investigation, Nigmatova surrendered the pharmacy license for Tera. Nigmatova did not agree to temporarily assume a managerial role pending licensure of a qualified owner. As a result, Tera was closed by the Board.

14. On or about February 4, 2026, the Board secured all drugs and medical records on Tera's premises. On February 5, 2026, Singson volunteered to properly secure the drugs and patient records on site and assist patients to transfer their prescription information to other pharmacies pending new ownership approved by the Board.

APPLICABLE LAW

15. Any person operating a pharmacy within this State shall obtain a license from the Board. NRS 639.230(1). Each license must be issued to a specific person and for a specific location and is not transferable. NRS 639.230(2).

16. The holder of a pharmacy license must file an application for a change of ownership at least 15 days prior to any change involving a transfer of 50 percent or more of the beneficial interest in the pharmacy. NAC 639.227(1). If the Board does not receive an application for change of ownership within the required timeframe, the Board may initiate proceedings to suspend the license to operate the pharmacy. NAC 639.227(3).

17. Pursuant to NRS 639.100(1), it is unlawful for any person to permit to be manufactured, distributed at wholesale, sold or dispensed, any drug, poison, medicine or chemical, or to dispense, or permit to be dispensed, any prescription of a practitioner, unless the person holds the appropriate certificate, license or permit and complies with the regulations adopted by the Board.

18. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(j).

19. In Nevada, written prescriptions for controlled substances must contain, among other things, the name and signature of the practitioner and the name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled. NRS 639.2353(2). All filled prescriptions must be retained on file for at least two years, and each prescription on file must be personally signed or initialed by the registered pharmacist who filled it. NRS 639.236(2); NAC 639.751.

20. Only a registered pharmacist or a registered pharmaceutical intern acting under the direct supervision of a registered pharmacist may identify, evaluate, and interpret a prescription. NAC 639.700(2). Pharmacists are responsible for verifying prescriptions prepared by pharmaceutical technicians, including, but not limited to the selection and strength of the drug and the dosage form. NAC 639.252(2). Pharmacists also have discretion not to fill a prescription if the prescription does not meet certain standards. NAC 639.752.

21. Performing any duties as the holder of a license, certificate or registration issued by the Board in an incompetent, unskillful, or negligent manner is unprofessional conduct and conduct contrary to the public interest. NAC 639.945(1)(i).

22. The Board may revoke or suspend the registration of any licensee who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

23. The Board may revoke or suspend the registration of any licensee who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

24. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

25. In lieu of, or in addition to revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE

Violation of State Regulation – Failure to Submit Change of Ownership
(Respondent Nigmatova)

26. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

27. As the seller, Nigmatova had a legal obligation pursuant to NAC 639.227(1) to file an application for a change of ownership at least 15 days prior to the transfer of the beneficial interest in the pharmacy at 8995 W. Flamingo Road, Suite 120, in Las Vegas, Nevada.

28. By failing to file an application for change of ownership pursuant to NAC 639.227(1), Nigmatova violated a Nevada regulation relating to the practice of pharmacy.

29. Nigmatova's conduct as alleged above amounts to a violation for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO

Permitting Unlicensed Practice
(Respondent Nigmatova)

30. As alleged above, on or about September 19, 2025, without giving prior notice to the Board, Nigmatova ostensibly caused the assets of Tera to be sold to Mahfouz.

31. When Nigmatova failed to file an application for change of ownership pursuant to NAC 639.227(1), Mahfouz, the putative new owner of Tera, did not legally obtain licensure to operate the pharmacy. As such, during the relevant time period, Mahfouz did not hold a license with the Board to engage in the practice of pharmacy in Nevada.

32. As alleged above, during the relevant time period, Mahfouz, on his own account and without knowledge or consent of the Board, continued to operate the pharmacy, including by continuing to receive, possess, store, hold for sale, and/or sell controlled substances and dangerous drugs, without a license as required by NRS 639.230.

33. By failing to file an application for change of ownership for Tera and causing putative owner Mahfouz, on his own account and without knowledge and consent of the Board, to operate the pharmacy location without an owner licensed by the Board pursuant to NRS

639.230(2), Nigmatova permitted Mahfouz to engage in unlicensed selling and/or dispensing of drugs in violation of NRS 639.100(1).

34. Respondent's conduct as alleged above amounts to a violation of NRS 639.100, as well as unprofessional conduct as defined by NAC 639.945(1)(j); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4); NRS 639.210(12); NAC 639.945(1)(j).

COUNT THREE
Unprofessional Conduct – Performing Duties in a Negligent Manner
(Respondent Singson)

35. As alleged above, between October 22, 2025 to November 4, 2025, Singson, as managing pharmacist at Tera, processed at least ten (10) prescriptions with missing information that is required by Nevada law or regulation. NRS 639.2353(2); NRS 639.236(2); NAC 639.751.

36. As the registered pharmacist on duty, Singson had a duty to verify, evaluate and interpret the prescriptions received at Tera. NAC 639.700(2); NAC 639.252(2); NAC 639.752.

37. By filling prescriptions that were not valid under Nevada law, Signson performed her duties as a licensee in a negligent manner. NAC 639.945(1)(i).

38. Singson's conduct as alleged above amounts to unprofessional conduct as defined by NAC 639.945(1)(i); therefore, the Board may impose administrative discipline. *See* NRS 639.210(4).

COUNT FOUR
Pharmacy/Pharmacy Owner Responsibility
(Respondent Tera Pharmacy)

39. As the pharmacy/pharmacy owner at which the unprofessional conduct and violations of law alleged herein occurred, Tera is responsible for those violations, including all errors and omissions of Respondent Nigmatova and Respondent Singson and any other pharmacy personnel in the course of conduct alleged above.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondents Tera Pharmacy, Nazakat Nigmatova, RPh, and Grace Singson, RPh.

DATED this 6th day of February 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration No. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondents.**	**Case No(s). 25-370-PH-S** **25-370-RPH-A-S** **25-370-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 4, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2)

copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of FEBRUARY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **GRACE SINGSON, RPH,** **Certificate of Registration No. 24727,** **Respondent.**	**Case No. 25-370-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

GRACE SINGSON, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Grace Singson, RPH
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

Craig K. Perry
Nevada Bar No. 3786
CRAIG K. PERRY & ASSOCIATES
6210 N. Jones Blvd., #753907
Las Vegas, Nevada 89136
T: (702) 228-4777
F: (702) 943-7520
cperry@craigperry.com

Attorney for Respondent
Grace Singson, RPH, Certificate of Registration No. 24727

FILED
FEB 20 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TERA PHARMACY,** **Pharmacy License No. PH04648,** **NAZAKAT NIGMATOVA, RPH,** **Certificate of Registration NO. 20601, and** **GRACE SINGSON, RPH,** **Certificate of Registration NO. 24727** **Respondents.**	**Case No. 25-370-PH-S** **25-270-RPH-A-S** **25-370-RPH-B-S** **ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION; AND NOTICE OF DEFENSE**

Respondent, above named, by and through her attorney, Craig K. Perry of the law firm of Craig K. Perry & Associates, that in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, and on advice of counsel, Respondent answers as follows:

1. Respondent admits, denies and alleges, with respect to each paragraph, as follows:

As to paragraph 1, Respondent admits the contents.

As to paragraphs 2 through 8, Respondent is without sufficient knowledge and therefore denies the contents.

As to paragraph 9, Respondent admits the contents.

As to paragraph 10a, Respondent admits she processed prescriptions as described, but is uncertain as to the number, and only to that extent denies the number prescribed in the manner indicated.

As to paragraph 10b, Respondent admits the contents.

As to paragraph 10c, Respondent admits she did not initial a number of the prescriptions set forth herein, does not recall the other missing information alleged, and therefore denies the remainder of this paragraph.

As to paragraph 10d, Respondent admits the contents.

As to paragraph 11, Respondent admits its contents based solely upon what she learned during the DEA investigation.

As to paragraph 12, Respondent is without sufficient knowledge, and there denies its contents.

As to paragraphs 13, based on information obtained solely from the Board of Pharmacy, Respondent admits the contents of this paragraph.

As to paragraphs 14 through 25, Respondent admits their contents.

As to paragraphs 26 through 34, Respondents is without sufficient knowledge and therefore denies their contents.

As to paragraph 35, Respondent admits she processed prescriptions with missing information, but denies the number that occurred, because she is without sufficient knowledge or recollection.

As to paragraphs 36 through 38, Respondent admits the contents of those paragraphs.

As to paragraphs 39, Respondent is without sufficient knowledge of its contents, and therefore denies.

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I hereby declare, under penalty of perjury, that the foregoing answer and notice of defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED: 2/19/2026

ID EEt5ZZhuH8SAjrUdNFX1fDFN

Grace Singson, RPH
Certification of Registration NO. 24727
Respondent

eSignature Details

Signer ID:	**EEt5ZZhuH8SAjrUdNFX1fDFN**
Signed by:	Grace Marielle Singson
Sent to email:	[redacted]gmail.com
IP Address:	24.234.94.90
Signed at:	Feb 19 2026, 2:03 pm PST

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6A

JOE LOMBARDO
Governor



HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

October 31, 2025

VIA CERTIFIED U.S. MAIL

Carolina Molina
Carolina Skin Care
9484 W Flamingo Road – Suite 300
Las Vegas, NV 89147

9489 0178 9820 3042 2524 01

Re: CEASE-AND-DESIST ORDER/CITATION & FINE: (Case No. 25-146-S)

Dear Ms. Molina:

The Nevada State Board of Pharmacy (Board) has determined that in the course of owning and operating Carolina Skin Care, located at 9484 W Flamingo Rd. in Las Vegas, you and your employees are unlawfully purchasing, storing, possessing, administering (including administration by injection) and/or furnishing dangerous drugs to patients who have not been examined and diagnosed by a Nevada-licensed practitioner and without direct practitioner supervision. This includes administering patient-specific medications to multiple patients and failing to maintain the security of the drugs in inventory. This constitutes a violation of state law, including, without limitation, NRS 200.840(1), NRS 454.213, NRS 454.221(1), NRS 454.311(1), NRS 454.316(1), NRS 454.321, NRS 454.356, NRS 454.510, NRS 585.520, NRS 639.100(1), NRS 639.268 and/or NRS 639.285.

You are hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST this unlawful activity. This notice shall serve as a CITATION pursuant to NRS 639.2895(2) for this violation.

The Board has assessed an administrative fine of five thousand dollars (**$5000.00**) pursuant to NRS 639.2895(3). This administrative fine must be paid within 30 days of receipt of this citation. Payment must be by personal, business, certified or cashier's check or money order made payable to "**State of Nevada, Office of the Treasurer**," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this citation. *See* NRS 639.2895(2). If you have any questions, please do not hesitate to contact Board staff at 775-850-1440.

Sincerely,

Nevada State Board of Pharmacy

Carolina Skin Care

9484 W Flamingo Rd. Suite 300
Las Vegas NV, 78147
[redacted]



December 8th, 2025

Dear Sir/Madam (Pharmacy Board team),

I hope this message finds you well.

On 25 November 2025, I submitted my response to your request via email, well ahead of the November 30th 2025 deadline. As I have not yet received any acknowledgment of receipt or further communication from your office, and in order to ensure that my response definitively reaches you, **I am today sending the complete set of documents by registered/postal mail**.

A copy of my original response is attached again for your immediate reference, and the hard copy sent by post today (8 December 2025) contains the same documents.

Thank you very much for your understanding, and please do not hesitate to contact me if anything further is required.

Yours sincerely,

Carolina Molina

Carolina Molina Owner & Operator Carolina Skin Care
9484 W Flamingo Road, Suite 300 Las Vegas, NV 89103
Phone: [redacted]

November 19, 2025

Nevada State Board of Pharmacy 985 Damonte Ranch Parkway, Suite 206 Reno, NV 89521

Via Certified Mail – Return Receipt Requested

Re: REQUEST FOR RECONSIDERATION AND APPEAL Case No. 25-146-S Cease-and-Desist Order, Citation & Fine – Issued October 31, 2025

Dear Members of the Board:

I am writing in formal response and appeal to the Cease-and-Desist Order, Citation, and $5,000 administrative fine issued on October 31, 2025.

Carolina Skin Care is a cosmetology establishment licensed and regulated exclusively by the Nevada State Board of Cosmetology. We do not perform, direct, supervise, or facilitate any medical procedures and have never held or required a pharmacy license.

Key Facts

1. All Medications Found in the Refrigerator and Cabinet Belonged Exclusively to Marika Kerr, APRN The prescription and dangerous drugs discovered in the refrigerator and in a cabinet during the Board's inspection were **owned, procured, and placed there exclusively by Marika Kerr, APRN —** a Nevada-licensed advanced practice registered nurse with full prescribing authority. Because some of these medications required refrigeration and others needed secure storage, Ms. Kerr personally placed them in the refrigerator and a designated cabinet for use only when she performed injectable aesthetic procedures on Carolina Skin Care clients.

2. Carolina Skin Care Never Purchased, Owned, or Exercised Control Over Any Medications Carolina Skin Care and its cosmetology-licensed employees have never purchased, owned, or exercised control over any prescription or dangerous drugs. The medications were present solely because they belonged to Ms. Kerr and were stored under her direction and responsibility.

3. All Medical Services Performed 100% by Marika Kerr, APRN Every medical assessment, prescribing decision, preparation, and administration of medication was performed independently by Ms. Kerr. Carolina Skin Care's role was limited to scheduling its own clients and providing the treatment room and storage access to Ms. Kerr.

4. No Representation as a Medical Practice or Pharmacy Carolina Skin Care has never held itself out as a medical practice or pharmacy.

In light of these facts, Carolina Skin Care did not purchase, store for business purposes, possess for dispensing, or administer dangerous drugs and therefore did not violate NRS Chapter 639. We respectfully request that the Board **reconsider and dismiss** both the citation and the $5,000 administrative fine.

We remain fully prepared to provide supporting documentation (including verification of Ms. Kerr's licensure and staff affidavits) and welcome an unannounced compliance inspection at any time.

Thank you for your time and consideration.

Sincerely,

Carolina Molina
Owner
Carolina Skin Care
Phone: [redacted]

FILED
JAN 7 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CAROLINA MOLINA, OWNER/OPERATOR OF CAROLINA SKIN CARE,** **Respondent.**	**CASE NO. 25-146-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.2895 and NRS 233B.121-.126, *inclusive*, on or about October 31, 2025, an Order to Cease-and-Desist/Citation and Fine was served upon Respondent Carolina Molina (Molina), owner/operator of Carolina Skin Care, alleging violations of Nevada law as set forth herein.

FACTUAL ALLEGATIONS

1. Molina owns and operates Carolina Skin Care, located at 9484 W Flamingo Rd. in Las Vegas, and is not a Nevada-licensed practitioner.

2. On or about April 16, 2025, a Board investigator in the course of an on-site investigation at Carolina Skin Care determined that Molina used the credentials of Marika Lenee Kerr, APRN (Kerr), Certificate of Registration No. CS26747, to purchase dangerous drugs, to maintain an unsecured inventory of dangerous drugs, and to access those medications outside Kerr's presence and without Kerr's supervision.

3. Molina independently accessed, possessed, furnished and/or administered dangerous drugs to patients, and provided on-site medical treatment at Carolina Skin Care, including the administration of dangerous drugs by injection, and including, without limitation,

glutathione, lipotropics, semaglutides, neuromodulators and dermal fillers, without direct practitioner supervision, to patients with whom no practitioner had established a bona fide therapeutic relationship, and for whom no practitioner had diagnosed or determined that a dangerous drug was medically necessary.

4. Molina conspired with Kerr to have Kerr regularly issue prescriptions for dangerous drugs falsely identifying Molina and other individuals as the patient to Meta Pharmacy Services, located at 8352 W. Warm Springs Road in Las Vegas, in order to obtain drugs for office administration to multiple patients, and administered patient-specific prescription medications to multiple patients.

5. On or about November 19, 2025, Molina appealed the Citation and Fine and requested a hearing before the Board.

APPLICABLE LAW

6. No person may possess or administer a dangerous drug in Nevada, including administration by injection, without specific statutory authority to do so. NRS 200.840(1); NRS 454.213; NRS 454.217; NRS 454.221; NRS 454.316; NRS 454.321; NRS 454.356; NRS 454.510; NRS 639.100(1).

7. No person may purchase supplies of dangerous drugs for office administration to patients excepted as permitted by NRS 639.268(1)(a) and NAC 639.757(4) and (5).

8. All dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

9. A practitioner may only prescribe a dangerous drug for a specific patient in conformance with NRS 454.223 and NRS 639.2353.

10. It is a felony offense to falsify a prescription for a dangerous drug or obtain a dangerous drug by a fraudulent prescription. NRS 454.311.

11. It is a felony offense to sell or administer a misbranded or adulterated drug. NRS 585.520; NAC 639.601(1).

12. It is a felony offense for an unlicensed person to sell, display or offer for sale a prescription drug. NRS 639.285.

13. It is a felony offense for an unlicensed person to furnish a dangerous drug to a patient. NRS 454.221(1).

14. It is a felony offense for an unlicensed person to perform a surgical procedure. NRS 200.840(1). "Surgical procedure" includes any minimally invasive medical procedure where a break in the skin is created. NRS 200.820.

COUNT ONE

Violations of State Law – Unlawful Purchase/Unsecured Inventory of Dangerous Drugs

15. By using Kerr's credentials to purchase and obtain dangerous drugs, to maintain an unsecured inventory of dangerous drugs, and to access those medications outside Kerr's presence and without Kerr's supervision, as alleged in paragraph 2 herein, Molina violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.268(1)(a), NAC 639.757(4) and (5) and/or NAC 639.898(1).

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COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

16. By independently accessing, possessing, furnishing and administering dangerous drugs to patients, and providing on-site medical treatment at Carolina Skin Care, including the administration of dangerous drugs by injection, and including, without limitation, glutathione, lipotropics, semaglutides, neuromodulators and dermal fillers, as alleged in paragraph 3 herein, Molina violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 200.840(1), NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356, NRS 454.510, NRS 639.100(1) and/or NRS 639.285.

COUNT THREE

Violations of State Law – Issuance of Fraudulent Prescriptions

17. By conspiring with Kerr to have Kerr regularly issue prescriptions for dangerous drugs falsely identifying Molina and other individuals as the patient to Meta Pharmacy Services in order to obtain drugs for office administration to multiple patients, as alleged in paragraph 4 herein, Molina violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223, NRS 454.311(1), NRS 454.316(2), NRS 639.2353, NRS 639.268(1)(a) and/or NAC 639.757(4) and (5).

COUNT FOUR

Violation of State Law - Administration of Patient-Specific Prescription Medications to Multiple Patients

18. By administering patient-specific prescription medications to multiple patients, as alleged in paragraph 4 herein, Molina violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.221(1), NRS 585.520(1) and/or (2) and/or NAC 639.601(1).

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision.

The Board has scheduled your hearing on this matter for Wednesday, March 4, at 9:00 a.m. or soon thereafter. The hearing will occur at Hilton Garden Inn Las Vegas Strip South, 7830 South Las Vegas Blvd., Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

Signed this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 7th day of January 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Carolina Skin Care
c/o Carolina Molina
9484 W. Flamingo Rd., Suite 300
Las Vegas, NV 89147

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PRIME PLUS LAKEVIEW,** **Respondent.**	**Case No. 25-110-V-O** **FIRST AMENDED STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.2895 and NRS 233B.121-.126, *inclusive*, on or about September 15, 2025, a Citation and Fine Order was served upon Respondent Prime Plus Lakeview, (Respondent) alleging violations of Nevada law as set forth herein.

FACTUAL ALLEGATIONS

1. Respondent is a pharmacy located at 3156 N. Clark St. in Chicago, Illinois.

2. Respondent does not hold a license issued by the Board to engage in wholesaling in the State of Nevada as required by NRS 639.233 and NAC 639.593.

3. First Choice Pharmacy, LLC is a pharmacy licensed by the Board and is located at 7260 S. Cimmaron Road, Suite 115, in Las Vegas, Nevada.

4. Rxeed is a wholesaling platform that represents itself on its website, www.rxeed.com, as an online marketplace that solicits and brokers the sales of prescription drug products between pharmacies across the United States.

5. Rxeed is not licensed to engage in business as a wholesaler in Nevada.

6. On August 25, 2023, through Rxeed, Respondent sold and/or shipped Vemlidy to First Choice Pharmacy in Las Vegas, Nevada, despite not having a license issued pursuant to NRS 639.233 and NAC 639.593. First Choice Pharmacy received the shipment in Nevada on September 1, 2023.

7. On or about October 10, 2024, the Board served an Order to Cease-and-Desist/Citation and Fine upon Rxeed for unlicensed wholesale distribution in Nevada. Rxeed satisfied the citation on June 12, 2025.

8. On or about September 15, 2025, following a Board investigation into Respondent's conduct in August and September 2023, the Board issued a Citation and Fine Order on Respondent.

9. On or about October 15, 2025, Respondent appealed the Citation and Fine Order and requested a hearing before the Board.

APPLICABLE LAW

10. Anyone who engages in the business of wholesale distribution or furnishing of drugs that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of NRS Chapter 639. NRS 639.100(3); NRS 639.233(1).

11. A person is "engaged in the business of furnishing" if the person solicits or accepts orders for drugs or devices whose sale in this State are restricted by chapters 453, 454 and/or 639 of the Nevada Revised Statutes. NRS 639.233(2).

12. "Wholesaler" means a wholesale distributor as defined by 21 CFR § 205.3(g). NRS 639.016.

13. Every wholesale distributor who engages in wholesale distribution of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

14. Pursuant to Nevada law, exceptions involving pharmacy-to-pharmacy sales apply only in specific circumstances. NRS 639.0155.

15. Wholesalers are subject to the licensing requirements specified in NRS 639.500, NRS 639.505, and NAC 639.593-5938, inclusive. Licensing of wholesalers is also subject to the requirements of federal law. 21 U.S.C. § 353(e)(l)(A); 21 CFR Part 205.

16. The Board may issue a Citation and Fine Order to individuals and/or entities that fail to comply with regulations adopted by the Board. NRS 639.100(1); NRS 639.2895.

17. The Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Violation of State Law: Wholesale Distribution in Nevada without a License

18. Respondent engaged in wholesale distribution into Nevada without first obtaining a license as required by NRS 639.233 and NAC 639.593.

19. Because of these actions, Respondent unlawfully engaged in wholesale distribution within the state. NRS 639.100(1), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205.

20. Having engaged in unlawful conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.100(1); NRS 639.2895.

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision.

The Board has scheduled your hearing on this matter for Wednesday, January 14, 2026, at 9:00 a.m. or soon thereafter. The hearing will occur at Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged

misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

Dated this 16th day of December 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of December 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Prime Plus Lakeview
3156 N Clark
Chicago, IL 60657

Prime Plus Lakeview
c/o Chandon S. Alexander, Esq.
400 South Seventh St, Suite 100
Las Vegas, NV 89101

And via Electronic Mail to: chandon@spartacuslawfirm.com

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
OCT 23 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PRIME PLUS LAKEVIEW,** **Respondent.**	**Case No. 25-110-V-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.2895 and NRS 233B.121-.126, *inclusive*, on or about September 15, 2025, a Citation and Fine Order was served upon Respondent Prime Plus Lakeview, (Respondent) alleging violations of Nevada law as set forth herein.

FACTUAL ALLEGATIONS

1. Respondent is a pharmacy located at 3156 N. Clark St. in Chicago, Illinois.

2. Respondent does not hold a license issued by the Board to engage in wholesaling in the State of Nevada as required by NRS 639.233 and NAC 639.593.

3. First Choice Pharmacy, LLC is a pharmacy licensed by the Board and is located at 7260 S. Cimmaron Road, Suite 115, in Las Vegas, Nevada.

4. Rxeed is a wholesaling platform that represents itself on its website, www.rxeed.com, as an online marketplace that solicits and brokers the sales of prescription drug products between pharmacies across the United States.

5. Rxeed is not licensed to engage in business as a wholesaler in Nevada.

6. On August 25, 2023, through Rxeed, Respondent sold and/or shipped Vemlidy to First Choice Pharmacy in Las Vegas, Nevada, despite not having a license issued pursuant to NRS 639.233 and NAC 639.593. First Choice Pharmacy received the shipment in Nevada on September 1, 2023.

7. On or about October 10, 2024, the Board served an Order to Cease-and-Desist/Citation and Fine upon Rxeed for unlicensed wholesale distribution in Nevada. Rxeed satisfied the citation on June 12, 2025.

8. On or about September 15, 2025, following a Board investigation into Respondent's conduct in August and September 2023, the Board issued a Citation and Fine Order on Respondent.

9. On or about October 15, 2025, Respondent appealed the Citation and Fine Order and requested a hearing before the Board.

APPLICABLE LAW

10. Anyone who engages in the business of wholesale distribution or furnishing of drugs that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of NRS Chapter 639. NRS 639.100(3); NRS 639.233(1).

11. A person is "engaged in the business of furnishing" if the person solicits or accepts orders for drugs or devices whose sale in this State are restricted by chapters 453, 454 and/or 639 of the Nevada Revised Statutes. NRS 639.233(2).

12. "Wholesaler" means a wholesale distributor as defined by 21 CFR § 205.3(g). NRS 639.016.

13. Every wholesale distributor who engages in wholesale distribution of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

14. Pursuant to Nevada law, exceptions involving pharmacy-to-pharmacy sales apply only in specific circumstances. NRS 639.0155.

15. Wholesalers are subject to the licensing requirements specified in NRS 639.500, NRS 639.505, and NAC 639.593-5938, inclusive. Licensing of wholesalers is also subject to the requirements of federal law. 21 U.S.C. § 353(e)(l)(A); 21 CFR Part 205.

16. The Board may issue a Citation and Fine Order to individuals and/or entities that fail to comply with regulations adopted by the Board. NRS 639.100(1); NRS 639.2895.

17. The Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Prescribing Controlled Substances Without a License

18. Respondent engaged in wholesale distribution into Nevada without first obtaining a license as required by NRS 639.233 and NAC 639.593.

19. Because of these actions, Respondent unlawfully engaged in wholesale distribution within the state. NRS 639.100(1), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205.

20. Having engaged in unlawful conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.100(1); NRS 639.2895.

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision.

The Board has scheduled your hearing on this matter for Wednesday, January 14, 2026, at 9:00 a.m. or soon thereafter. The hearing will occur at Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged

misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

Dated this 23rd day of OCTOBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23RD day of OCTOBER 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Prime Plus Lakeview
c/o Chandon S. Alexander, Esq.
400 South Seventh St, Suite 100
Las Vegas, NV 89101

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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FILED
JAN 7 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **OXUS AMERICA, INC,** **Respondent.**	**Case Nos. 25-470-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED, PLEASE TAKE NOTICE THAT:

On or about December 15, 2025, pursuant to NRS 639.2895, the Nevada State Board of Pharmacy (Board) issued a Cease-and-Desist/Citation-and-Fine (Citation) to Oxus America, Inc. (Oxus). On December 18, 2025, Oxus requested a hearing before the Board pursuant to NRS 639.2895(2). For purposes of the hearing, it is alleged that:

FACTUAL ALLEGATIONS

1. Oxus is a company that specializes in medical devices and gas separation technology. Oxus is located at 175 Kay Industrial Drive, Orion Township, Michigan.

2. Oxus is ISO 13485 certified. ISO 13485 is the internationally recognized standard for quality management systems in the design and manufacture of medical devices.

3. Oxus is also a U.S. Food and Drug Administration (FDA) registered manufacturer.

4. Oxus sold and/or shipped Stationary Sieve Replacements in Reno, Nevada from its Michigan facility.

5. Stationary Sieve Replacements incorporate molecular sieve technology and are intended to replace an identical component of an oxygen concentrator. Molecular sieve technology separates oxygen from carbon dioxide and nitrogen.

6. Stationary Sieve Replacements are shipped and sold only to medical products providers. A trained technician must install the Stationary Sieve Replacement.

7. Mui Lee, the Board's investigator, conducted a routine inspection of Bennett Medical Services, also known as Adapt Health. During her inspection, Inspector Lee discovered an invoice from Oxus for Stationary Sieve Replacements.

8. Inspector Lee attempted to contact Oxus to inquire about the invoice; however, no representatives responded to phone calls or emails.

9. Oxus received the Board's citation on or about December 15, 2025. The Board cited Oxus for engaging in the unlawful wholesale distribution of prescription only drugs without the required Nevada wholesale license.

10. On December 18, 2025, Oxus submitted an appeal arguing that the Stationary Sieve Replacements are not prescription devices as they are just a repair component of an oxygen concentrator. Oxus also disagreed that it is a wholesaler as defined by Nevada regulations.

APPLICABLE LAW

11. Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license. NRS 639.233, NAC 639.6942.

12. Pursuant to NRS 639.016, a "wholesaler" includes any person or business that distributes drugs or devices that are restricted by federal law to sale by or on the order of a physician to a person other than the consumer or patient.

13. "Medical products wholesaler" means a person who sells, leases, or otherwise provides medical products to a health care facility, agency, practitioner or provider in Nevada. NAC 639.6937

14. The term "drug" includes "articles and *devices* intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" including "articles intended for use as a *component* of any article specified." (*italics* added). NRS 639.007. Similarly, 21 U.S.C. § 321(h)(1) defines a "device" to include any instrument, apparatus, or other similar or related

article, including any *component, part, or accessory,* that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or that is intended to affect the structure or any function of the body (emphasis added).

15. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6935. It also includes "medical devices, equipment, supplies or gases" which are governed by any other board or agency other than the Board of Pharmacy.

16. The FDA is a U.S. government agency under the Department of Health and Human Services.

17. An oxygen concentrator is a "device" as that term is defined at 21 U.S.C. § 321(h). The product's purpose is for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.

18. Oxygen concentrators are "prescription devices" within the meaning of 21 CFR § 801.109. Oxygen concentrators incorporate molecular sieve technology to separate oxygen from carbon dioxide and nitrogen.

19. Devices that use molecular sieve technology are categorized by the FDA as class II medical devices. *See* 21 CFR § 868.5440. This means that they may not be sold at retail except pursuant to a prescription. *See* 21 CFR § 860.3; 21 CFR § 801.109.

20. Under both state and federal law, the term "device" means and includes the component parts of the device. *See* NRS 639.007; 21 U.S.C. § 321(h)(1). By definition, if an oxygen concentrator may not be sold at retail without a prescription, its component parts may not be sold at retail without a prescription.

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COUNT ONE

Violation of State Law: Wholesale Distribution in Nevada without a License

21. The Stationary Sieve Replacement is an FDA regulated component that is critical to the prescription-only oxygen concentrator. Because the component materially impacts physician-prescribed oxygen therapy and is not safe for use without professional installation, it is restricted to prescription use.

22. Respondent engaged in wholesale distribution into Nevada of an FDA regulated component device without first obtaining a license required by NRS 639.233 and NAC 639.593.

23. Because of these actions, Respondent unlawfully engaged in wholesale distribution within the state. NRS 639.100(1), 21 U.S.C. § 353(e)(l)(A) and/or 21 CFR Part 205.

24. Having engaged in unlawful conduct as alleged above, Respondent is subject to an administrative fine of $5,000. NRS 639.100(1); NRS 639.2895.

25. In addition to collecting the $5,000 fine as authorized by NRS 639.2895, the Board may recover its costs of investigation and prosecution pursuant to NRS 622.400.

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2); NRS 233B.127(3). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.127(3); NRS 622A.300(1) and (3). If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

The Board has scheduled your hearing on this matter for March 4, 2026, at 9:00 a.m. or soon thereafter. The hearing will occur at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. You may request and the Board may at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session. NRS 241.030 and NRS 241.033.

DATED this 7th day of January 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of January, 2026, I personally served a true and correct copy of the foregoing **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** by placing a copy by Certified U.S. Mail and Standard U.S. mail to the following:

Oxus America, Inc
175 Kay Industrial Drive
Orion Township, MI 48359

And by sending a copy via email to:

Jessica Shopp (jshopp@oxusamerica.com)
Gary Abusamra (gabusamra@oxusamerica.com)
Ryan Lenarcic (rlenarcic@oxusamerica.com)

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: ActivStyle, LLC

MDEG Physical Address: 7259 West Sahara Ave, Suite 100

City: Las Vegas State: NV Zip: 89117

Mailing Address (if different from physical address): 1055 West Gate Drive, Suite 100

City: St. Paul State: MN Zip: 55114

Telephone: (702)330-4823 Website: www.activstyle.com

Email: compliance@activstyle.com

Name of MDEG Administrator (NAC 639.694): Nicole Wysocki

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: **Other: Incontinence, urological, ostomy & wound care supplies**
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Nicole Wysocki
	Telephone: (702)330-4823

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:30-12;	■ Tue: 8:30-12;	■ Wed: 8:30-12;	■ Thurs: 8:30-12;	■ Fri: 8:30-12;
☐ Sat: 12:30-4:30	☐ Sun: 12:30-4:30	☐ Holidays: 12:30-4:30	12:30-4:30	12:30-4:30

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare:1265720001; 1265720004; 1265720005; Medicaid: MS-006709293; ND-1453851; OH-2227423; AK-1021830;
AR-203671716; AZ-183206; CT-004268844; ID-807670400; IL-41187546300(01),(02); WI-100159571; OK-200106290A
ID-300026903; LA-2357387; MD-DME 014083000; MT-0048074; NE-10026339600; OH DODD-9801727; WY-227567800
PA-1018588800004; TX-286522202; UT-411875463010; VA-30015056720001; WA-1009967;(RI, SD, IA, MN)-1417954165

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota

Parent Company (if any): ActivStyle Health Holdings, LLC

Corporation/Organization Name: ActivSyle, LLC

Mailing Address: 277 Park Avenue

City: New York State: NY Zip: 10172

Telephone: (651) 760-7275 Email: darrell.rawlings@activstyle.com

Contact Person Name: Darrell Rawlings

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Darrell Rawlings

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/19/2026

Date

Board Use Only	Date Received: 1120126	Amount: $500CC

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/16/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Northeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com
INSURED ActivStyle, Inc. 7259 West Sahara Ave., Suite 100 Las Vegas, NV 89117	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Mitsui Sumitomo Insurance USA Inc — 22551 INSURER B: Mitsui Sumitomo Insurance Company of Ameri — 20362 INSURER C: Starr Surplus Lines Insurance Company — 13604 INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W42388720 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [X] LOC [ ] OTHER:			GL2122504	10/01/2025	10/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 2,000,000 $ 2,000,000 $ 10,000 $ 2,000,000 $ 10,000,000 $ 10,000,000
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
B	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			UMB5000870	10/01/2025	10/01/2026	EACH OCCURRENCE AGGREGATE	$ 8,000,000 $ 8,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
C	Spec Prof Liab			1001236648251	05/01/2025	05/01/2026	Per Claim/Aggregate Retention	$3,000,000 $50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Palmetto GBA
NPWEST DMEPOS
PO Box 100142
Columbia, SC 29202-3142

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Patricia A Forry

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Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	ActivStyle, LLC
Date Filed:	06/11/2020
File Number:	1162851100081
Minnesota Statutes, Chapter:	322C
Home Jurisdiction:	Minnesota

This certificate has been issued on: 09/17/2025

THE GREAT SEAL OF THE STATE OF MINNESOTA
MNI SÓTA MAKOCE

Steve Simon
Secretary of State
State of Minnesota

ActivStyle
Your Medical Supply Advocate

Senior Care Services | ADVOCATE MEDICAL SERVICES | HOME WELLNESS INC. MEDICAL SUPPLIES FOR THE HOME | M.A.R.Y. Medical ActivStyle | Champlain Valley Brace and Limb | All American Home Aid

Board of Directors Information

Darrell Rawlings- darrell.rawlings@activstyle.com
DOB: [redacted]
Title- CEO
Office address: 105 Westgate Drive, Suite 100 St. Paul, MN 55114

Jeremy Yap- Jeremy.yap@sumitomocorp.com
DOB: [redacted]
Title- Vice President of Business Growth & General Manager
Address: [redacted]

Takeshi Hara- Takeshi.hara@sumitomocorp.com
DOB: [redacted]
Title- Senior Director
Address: [redacted]

Hiroshi Jasagawa- Hiroshi.jasagawa@sumiotomocorp.com
DOB: [redacted]
Title- General Manager
Address: [redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site ActivStyle, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 7259 West Sahara Ave, Suite 100

City Las Vegas State NV Zip 89117

Mailing Address (if different from physical address) 1055 West Gate Drive, Suite 100

City St. Paul State MN Zip 55114

Telephone (702)330-4823 Website activstyle.com

Licensing Company Email credentialing@activstyle.com

Section 2: Personal Information

First JEREMY Middle _____ Last YAP

Alias(es, nicknames, name changes, etc.) —

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State NY Zip [redacted]

Telephone [redacted] Email JEREMY.YAP@SUMITOMOCORP.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
NORTHWESTERN UNIVERSITY		09/00 - 06/04	
Address	**City**	**State**	**Zip**
601 UNIVERSITY PLACE	EVANSTON	IL	60208
Diploma/Degree obtained, if any			
BACHELOR OF ARTS			

School Name		From - To (MM/YY – MM/YY)	
CRESCENT SCHOOL		09/96 - 06/00	
Address	**City**	**State**	**Zip**
2365 BAYVIEW AVENUE	TORONTO, ONTARIO,	CANADA	M2L 1A2
Diploma/Degree obtained, if any			
HIGH SCHOOL DEGREE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/19 - PRESENT	[redacted]	[redacted]	NY	[redacted]
07/18 - 07/19			NY	
07/14 - 07/18			NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
SUMITOMO CORPORATION OF AMERICAS			07/13- PRESENT
Business Address	**City**	**State**	**Zip**
277 PARK AVENUE 15TH FLOOR	NEW YORK	NY	10172
Phone	**Title**		
847-274-7246	GENERAL MANAGER		
Description of Duties			
OVERSEE NEW AND EXISTING INVESTMENTS			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JEREMY YAP

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

JANUARY 16, 2026

Date

Please have this section completed in the presence of a Notary Public.

State of NEW YORK, ss. County of NEW YORK

I, JEREMY YAP, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

JANUARY 16, 2026

Date

Subscribed and Sworn to before me this 16th day of January, 2026.

Notary Public Signature

CHRISTOPHER O MOORE-DOLL
Notary Public - State of New York
No. 01MO0002032
Qualified in KINGS
My Commission Expires February 27, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG ActivStyle. LLC MDEG License # (if applicable) _____

Physical Address 7259 West Sahara Ave, Suite 100

City Las Vegas State NV Zip 89117

Mailing Address (if different from physical address) 1055 Westgate Drive, Suite 100

City St. Paul State MN Zip 55114

Telephone (702)330-4823 Website activstyle.com

Licensing Company Email Credentialing@activstyle.com

Section 2: Personal Information

First Nicole Middle Frances Last Wysocki-Tucker

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City [redacted] State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Northwest Health Careers			01/2008-06/2009
Address	**City**	**State**	**Zip**
7398 Smoke Ranch Rd.	Las Vegas	NV	89128
Diploma/Degree obtained, if any			
Diploma Medical Assisting			

School Name			From - To (MM/YY – MM/YY)
Waianae High School			9/00 - 6/04
Address	**City**	**State**	**Zip**
86-251 Farrington Hwy	Waianae	HI	96792
Diploma/Degree obtained, if any			
G.E.D			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/24 - 10/26	[redacted]	[redacted]	NV	[redacted]
5/22 - 8/24			NV	
1/12 - 5/22			NV	
From - To (MM/YY – MM/YY)			State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
CVS Pharmacy		11/2007-Present	
Business Address	**City**	**State**	**Zip**
8320 W. Cheyenne Ave.	Las Vegas	NV	89129
Phone	**Title**	**Number of Employed Hours**	
702-658-1229	Operations Manager		
Description of Duties			
Direct daily store operations, includes staffing, scheduling & inventory control. Ensure compliance & company policies, healthcare regulations & safety standards.			

Business Name		From - To (MM/YY – MM/YY)	
Nevada Orthopedic & Spine Center		1/22 - 1/24	
Business Address	**City**	**State**	**Zip**
7466 W. Washington Ave. #160	Las Vegas	NV	89128
Phone	**Title**	**Number of Employed Hours**	
702-878-0393	Lead Medical Assistant		
Description of Duties			
Supervised & trained Medical assistants, maintained EHR with accuracy & confidentiality. Coordinated patient scheduling, intake, follow-up Care.			

Business Name		From - To (MM/YY – MM/YY)	
OptumRx		1/2015 - 12/21	
Business Address	**City**	**State**	**Zip**
Briova Dr.	Las Vegas	NV	89113
Phone	**Title**	**Number of Employed Hours**	
1-800-356-3477	Patient Care Coordinator		
Description of Duties			
Verified health insurance eligibility & coverage for patients. Managed patient communications & prescription processing assisted in resolving patient issues & concerns.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9.12.2025
Date

I, Nicole Wysocki-Tucker, certify that as the MDEG Administrator for

_____,

that I (initial that you have read and meet the following requirements):

1. NT Have a high school diploma or its equivalent;
2. NT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. NT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. NT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicole Wysocki-Tucker
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9.12.2025
Date

Board Use Only	Date Received: 11/20/25

7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
■ Name Change*	M 03088	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: FOOT CARE STORE,LLC D/B/A DIA-FOOT

MDEG Physical Address: 4280 WEST WINDMILL LANE STE 111

City: LAS VEGAS State: NV Zip: 89139

Mailing Address (if different from physical address): 3281 FAIRLANE FARMS RD, STE 7

City: WELLINGTON State: FL Zip: 33414

Telephone: 561-791-1213 Website: WWW.DIA-FOOT.COM

Email: JAY@DIA-FOOT.COM

Name of MDEG Administrator (NAC 639.694): SARA MICHELLE SIMONSON

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
■ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: DIABETIC FOOTWEAR
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____ Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
▣ Mon: 9-5	▣ Tue: 9-5	▣ Wed: 9-5	▣ Thurs: 9-5	▣ Fri: 9 - 5
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
1568057057

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FLORIDA

Parent Company (if any): PACIFIC FOOTWEAR COMPANY,INC D/B/A PRIORTY FOOTWEAR

Corporation/Organization Name: FOOT CARE STORE, LLC D/B/A DIA-FOOT

Mailing Address: 3281 FAIRLANCE FARMS ROAD STE 7

City: WELLINGTON State: FL Zip: 33414

Telephone: 561-791-1213 Email: JAY@DIA-FOOT.COM

Contact Person Name: JAY JOSEPHSON

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JAY Tayloson

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/16/26

Date

Board Use Only	Date Received: 1/21/26	Amount: NO payment

Kristy Langston

From: jay@dia-foot.com
Sent: Monday, January 26, 2026 3:55 AM
To: Kristy Langston
Subject: RE: [EXTERNAL] [External Message] MDEG Change of Ownership Applications

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good Morning,

The following are the responses to the deficiencies you requested.

- Please provide a summary of the ownership change being implemented.

100% ownership of Foot Care Store, LLC d/b/a Dia-Foot was transferred from Dr. Robert Gaynor to Pacific Footwear Company, Inc. d/b/a Priority Footwear.

- Are any owners a health professional as defined by NRS 639.0125 (see below)?

No.

- If there are any individuals/shareholders/partners with 10% or greater ownership of the company a personal history application must be provided.

None.

- A list of officers/directors

Foot Care Store, LLC does not have any officers/directors. Robert Gaynor is the Manager

If you requiring anything further please let me know.

Jay A. Josephson
Chief Financial Officer
Dia-Foot
3281 Fairlane Farms Rd., Ste 7
Wellington, FL 33414
Jay@dia-foot.com

561-791-1213

From: "Kristy Langston" <klangston@pharmacy.nv.gov>
Sent: 1/22/26 1:30 PM
To: "jay@dia-foot.com" <jay@dia-foot.com>
Subject: [EXTERNAL] [External Message] MDEG Change of Ownership Applications

CAUTION: This email originated from outside of this organization. Do not click on links or open attachments unless you recognize the sender and know the content is safe.

Thank you for submitting change of ownership applications for Dia-Foot's MDEG license. Deficiencies have been identified.

- Please provide a summary of the ownership change being implemented.
- Are any owners a health professional as defined by NRS 639.0125 (see below)?
- If there are any individuals/shareholders/partners with 10% or greater ownership of the company a personal history application must be provided.
- A list of officers/directors

NRS 639.0125 "Practitioner" defined. "Practitioner" means:

1. A physician, dentist, veterinarian or podiatric physician who holds a license to practice his or her profession in this State;

2. A hospital, pharmacy or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this State;

3. An advanced practice registered nurse who has been authorized to prescribe controlled substances, poisons, dangerous drugs and devices;

4. A physician assistant who:

(a) Holds a license issued by the Board of Medical Examiners; and

(b) Is authorized by the Board to possess, administer, prescribe or dispense controlled substances, poisons, dangerous drugs or devices under the supervision of a physician as required by chapter 630 of NRS;

5. A physician assistant who:

(a) Holds a license issued by the State Board of Osteopathic Medicine; and

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 1/14/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
The Baldwin Group Southeast LLC
4211 W Boy Scout Blvd Ste 800
Tampa FL 33607

License#: L002281
ANODLLC-01

CONTACT NAME:
PHONE (A/C, No, Ext): 813-984-3200 **FAX (A/C, No):** 813-984-3201
E-MAIL ADDRESS: Certificates@baldwin.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Hanover Insurance Company	22292
INSURER B : Hanover American Insurance Co	36064
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Foot Care Store, LLC DBA Dia-Foot
Foot Care Store, Inc.
3281 Fairlane Farms Road
Wellington FL 33414

COVERAGES **CERTIFICATE NUMBER:** 1064393639 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			ZHJ-M000401-00	3/27/2025	3/27/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			AWJ J900007	4/13/2025	4/13/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			UHJ 9938089 03	4/13/2025	4/13/2026	EACH OCCURRENCE	$ 3,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 3,000,000
	DED X RETENTION $ 0						Products Excluded	$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products Liability			LHJ 9938103 03	4/13/2025	4/13/2026	Claim Limit / Claim Deductible	5,000,000 / 50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: 4280 West Windmill Lane, Ste 111 Las Vegas NV 89139

CERTIFICATE HOLDER

Nevada State Pharmacy Board
985 Damonte Ranch Parkway
Suite 206
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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State of Florida
Department of State

I certify from the records of this office that FOOT CARE STORE, LLC is a limited liability company organized under the laws of the State of Florida, filed on December 16, 2025, effective January 16, 1996.

The document number of this limited liability company is L25000552011.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Eighth day of January, 2026

Secretary of State

Tracking Number: 3769208353CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG FOOT CARE STORE LLC, dba DIA-FOOT MDEG License # (if applicable) MP03088

Physical Address 4280 WEST WINDMILL LANE, SUITE 111

City LAS VEGAS State NV Zip 89139

Mailing Address (if different from physical address) 3281 FAIRLANE FARMS RD

City WELLINGTON State FL Zip 33414

Telephone 702-970-7166 Website WWW.DIA-FOOT.COM

Licensing Company Email JAY@DIA-FOOT.COM

Section 2: Personal Information

First SARA Middle MICHELLE Last SIMONSON

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State NV Zip [redacted]

Telephone [redacted] Email MICHELLE@DIA-FOOT.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
PEACE COLLEGE		08/02-05/06	
Address	**City**	**State**	**Zip**
15 EAST PEACE ST	RALEIGH	NC	27604
Diploma/Degree obtained, if any			
BACHELORS - BIOLOGY			

School Name		From - To (MM/YY – MM/YY)	
PEACE COLLEGE		08/02-08/04	
Address	**City**	**State**	**Zip**
15 EAST PEACE ST	RALEIGH	NC	27604
Diploma/Degree obtained, if any			
ASSOCIATES OF ARTS			

School Name		From - To (MM/YY – MM/YY)	
WELLINGTON HIGH SCHOOL		08/99-05/02	
Address	**City**	**State**	**Zip**
2101 GREENVIEW SHORE BLVD	WELLINGTON	FL	33414
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/25-CURRENT	[redacted]	[redacted]	NV	[redacted]
04/21-04/25			NV	
05/19-03/21			FL	
12/16-04/19			FL	
06/13-11/16			FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
DIA-FOOT			04/21-CURRENT	
Business Address	**City**		**State**	**Zip**
4280 WEST WINDMILL LN, SUITE 111	LAS VEGAS		NV	89139
Phone	**Title**		**Number of Employed Hours**	
702-970-7166	CHIEF OPERATING OFFICER		+13,000 HRS	
Description of Duties				
RESPONSIBLE FOR EXECUTIVE LEADERSHIP WITH CEO AND CFO IN OPERATING ALL ASPECTS OF THE COMPANY. CURRENT DESIGNATED REP, MDEG ADMINISTRATOR, ABC CERTIFIED PEDORTHIST FOR FACITLY.				

Business Name			From - To (MM/YY – MM/YY)	
DIA-FOOT			07/20-03/21	
Business Address	**City**		**State**	**Zip**
3281 FAIRLANE FARMS RD, SUITE 4	WELLINGTON		FL	33414
Phone	**Title**		**Number of Employed Hours**	
561-791-1213	FACILITY MANAGER - ASSISTANT OPERATIONS MGR		+1,200	
Description of Duties				
GENERAL OVERSIGHT OF ALL DAILY OPERATIONS WITH EMPHASIS ON COMPLIANCE, AND ENFORCING POLICIES AND PROCEDURES. RESPONSIBLE FOR THE FITTING AND DISPENSING OF DIABETIC SHOES/INSERTS				

Business Name			From - To (MM/YY – MM/YY)	
NEW BALANCE SOUTH FLORIDA			11/13-10/19	
Business Address	**City**		**State**	**Zip**
6000 GLADES RD, STE 1234	BOCA RATON		FL	33431
Phone	**Title**		**Number of Employed Hours**	
	MANAGER - FIT SPECIALIST		+21,000	
Description of Duties				
SEASONED RETAIL PROFESSIONAL WITH MANAGING DAILY OPERATIONS IN A FAST PACE ENVIRONMENT. SPECIALIZED IN IMPLEMENTING A ROBUST DOCTOR REFERRAL AND WELLNESS PROGRAM.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

01/13/2026
Date

I, SARA MICHELLE SIMONSON, **certify that as the MDEG Administrator for**

FOOT CARE STORE, LLC dba DIA-FOOT,

that I (initial that you have read and meet the following requirements):

1. SMS Have a high school diploma or its equivalent;
2. SMS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SMS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SMS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SARA SIMONSON

Print Name (First, Last)

Sara M. Simonson

Original Signature (electronic, copies or stamps not accepted)

01/15/2026

Date

Board Use Only	Date Received:

7C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: THE RE-HABIT WELLNESS CASTLE

MDEG Physical Address: 621 S 10TH ST

City: LAS VEGAS State: NV Zip: 89101

Mailing Address (if different from physical address): 621 S 10TH ST

City: LAS VEGAS State: NV Zip: 89101

Telephone: 725.577.2233 Website: N/A

Email: REHABITWELLNESSINC@GMAIL.COM

Name of MDEG Administrator (NAC 639.694): ANDRINA VASQUEZ-SANCHEZ

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	■ Medical Gases**
☐ Pharmacies[a]	■ Respiratory Equipment**
☐ Practitioners[a]	■ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	■ Parenteral and Enteral Equipment**
☐ Clinics[a]	■ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: INCONTINENCE/URILOGICAL
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: ANDRINA VASQUEZ Telephone: 702.376.6547

Check the Days the Business will be Opened and provide the Hours of Operation				
☐ Mon: VIRTUAL 24 H	☐ Tue: VIRTUAL 24 H	☐ Wed: VIRTUAL 24 H	☐ Thurs: VIRTUAL 24 H	☐ Fri: VIRTUAL 24 H
☐ Sat: VIRTUAL 24 H	☐ Sun: VIRTUAL 24 H	☐ Holidays: VIRTUAL 24 H		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
N/A - WILL BE APPLYING FOR MEDICARE AND MEDICAID AND TO US GOVERMENT

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials: N/A	%: 0
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): N/A

Corporation/Organization Name: THE RE-HABIT WELLNESS CASTLE

Mailing Address: 621 S 10TH ST

City: LAS VEGAS State: NV Zip: 89101

Telephone: 725.577.2233 Email: REHABITWELLNESSINC@GMAIL.COM

Contact Person Name: ANDRINA VASQUEZ

Section 7: Partnership

Partnership Name: NONE

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: ANDRINA VASQUEZ SANCHEZ

Business Name: THE RE-HABIT WELLNESS CASTLE

Business Address: 621 S 10TH ST

City: LAS VEGAS State: NV Zip: 89101

Telephone: 7255772233 Email: REHABITWELLNESSINC@GMAIL.COM

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List of all Officers and Directors.	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANDRINA VASQUEZ-SANCHEZ

Print Name of Authorized Person Submitting Application

Andrina Vasquez

Original signature of Authorized Person (copies or stamps not accepted)

10/01/2025

Date

Board Use Only	Date Received: 11/5/25	Amount: 500-CK-1001

Policy Number:

Date Entered: 1/29/2026

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
1/29/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	Harrison Insurance Agency LLC www.timharrisoninsuranceagency.com 3470 East Russell Road, Suite 206 Las Vegas, NV 89120	CONTACT NAME: TIM HARRISON PHONE (A/C, No, Ext): (702)674-9632 FAX (A/C, No): (702)674-9633 E-MAIL ADDRESS: t.harrisonins@yahoo.com	
		INSURER(S) AFFORDING COVERAGE	NAIC #
		INSURER A: KINSALE INSURANCE COMPANY	
INSURED	RE-HABIT WELLNESS INC DBA RE-HABIT WELLNESS CASTLE 621 S 10TH STREET LAS VEGAS, NV 89101	INSURER B:	
		INSURER C:	
		INSURER D:	
		INSURER E:	
		INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	☒ COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	☐ CLAIMS-MADE ☒ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
				0100425946-0	1/27/2026	1/27/2027	MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	☒ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ N/A						E.L. EACH ACCIDENT	$
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	PRODUCT RECALL EXPENSE DATA BREACH EXPENSE			0100425946-0	1/27/2026	1/27/2027	$100,000 $100,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

INVACARE AMERICA
1 INVACARE WAY
ELYRIA, OH 44035

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

TIM HARRISON

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Policy Number:

Date Entered: 1/29/2026

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 1/29/2026

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PRODUCER Harrison Insurance Agency LLC www.timharrisoninsuranceagency.com 3470 East Russell Road, Suite 206 Las Vegas, NV 89120	CONTACT NAME: TIM HARRISON PHONE (A/C, No, Ext): (702)674-9632 FAX (A/C, No): (702)674-9633 E-MAIL ADDRESS: t.harrisonins@yahoo.com
INSURED RE-HABIT WELLNESS INC DBA RE-HABIT WELLNESS CASTLE 621 S 10TH STREET LAS VEGAS, NV 89101	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: KINSALE INSURANCE COMPANY INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	☒ COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ☒ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ☒ POLICY ☐ PRO-JECT ☐ LOC OTHER:			0100425946-0	1/27/2026	1/27/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 5,000 $ 1,000,000 $ 2,000,000 $ 2,000,000
	AUTOMOBILE LIABILITY ☐ ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	☐ UMBRELLA LIAB ☐ OCCUR ☐ EXCESS LIAB ☐ CLAIMS-MADE ☐ DED ☐ RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) ☐ Y/N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					☐ PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
A	PRODUCT RECALL EXPENSE DATA BREACH EXPENSE			0100425946-0	1/27/2026	1/27/2027	$100,000 $100,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

MEDLINE INDUSTRIES
1960 MIRCO WAY
RIALTO, CA 92396

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

TIM HARRISON

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Policy Number:

Date Entered: 1/29/2026

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 1/29/2026

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PRODUCER	Harrison Insurance Agency LLC www.timharrisoninsuranceagency.com 3470 East Russell Road, Suite 206 Las Vegas, NV 89120	CONTACT NAME: TIM HARRISON PHONE (A/C, No, Ext): (702)674-9632 FAX (A/C, No): (702)674-9633 E-MAIL ADDRESS: t.harrisonins@yahoo.com	
		INSURER(S) AFFORDING COVERAGE	NAIC #
		INSURER A : KINSALE INSURANCE COMPANY	
INSURED	RE-HABIT WELLNESS INC DBA RE-HABIT WELLNESS CASTLE 621 S 10TH STREET LAS VEGAS, NV 89101	INSURER B :	
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		INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	☒ COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ☒ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ☒ POLICY ☐ PRO-JECT ☐ LOC OTHER:			0100425946-0	1/27/2026	1/27/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 5,000 $ 1,000,000 $ 2,000,000 $ 2,000,000
	AUTOMOBILE LIABILITY ☐ ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	☐ UMBRELLA LIAB ☐ OCCUR ☐ EXCESS LIAB ☐ CLAIMS-MADE ☐ DED ☐ RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N ☐ N/A If yes, describe under DESCRIPTION OF OPERATIONS below						☐ PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
A	PRODUCT RECALL EXPENSE DATA BREACH EXPENSE			0100425946-0	1/27/2026	1/27/2027	$100,000 $100,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

NEVADA STATE BOARD OF PHARMACY
985 DAMANTE RANCH PKWY, STE 206
RENO, NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

TIM HARRISON

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SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **The Re-Habit Wellness Castle** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 04/30/2025, and in good standing in this State.

I further certify that the above DOMESTIC CORPORATION (78) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 01/29/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601296450263
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE President:

Name	Country
Andrina Vasquez-Sanchez	USA

Address	City	State	Zip/Postal Code
[redacted]	[redacted]	NV	[redacted]

CORPORATION, INDICATE THE Secretary:

Name	Country
Andrina Vasquez-Sanchez	USA

Address	City	State	Zip/Postal Code
[redacted]	[redacted]	NV	[redacted]

CORPORATION, INDICATE THE Treasurer:

Name	Country
Andrina Vasquez-Sanchez	USA

Address	City	State	Zip/Postal Code
[redacted]	[redacted]	NV	[redacted]

CORPORATION, INDICATE THE Director:

Name	Country
Andrina Vasquez-Sanchez	USA

Address	City	State	Zip/Postal Code
[redacted]	[redacted]	NV	[redacted]

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X Andrina M Vasquez-Sanchez
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Director
Title

04/30/2025
Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: THE RE-HABIT WELLNESS CASTLE MDEG License # (if applicable): _____

Physical Address: 621 S 10TH ST

City: LAS VEGAS State: NV Zip: 89101

Mailing Address (if different from physical address): 621 S 10TH ST

City: LAS VEGAS State: NV Zip: 89101

Telephone: 725.577.2233 Website: _____

Licensing Company Email: REHABITWELLNESSINC@GMAIL.COM

Section 2: Personal Information

First: ANDRINA Middle: MARIE Last: VASQUEZ-SANCHEZ

Alias(es, nicknames, name changes, etc.): ANGI VASQUEZ

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 621 S 10TH ST

City: LAS VEGAS State: NV Zip: 89101

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
PAHRUMP VALLEY HIGH SCHOOL		05-06	
Address	City	State	Zip
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
HIGH TECH INSTITUTE		2006-2008	
Address	City	State	Zip
Diploma/Degree obtained, if any			
ASSOCIATES OF APPLIES SCHENCE IN SURGICAL TECHNOLOGY			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF PHOENIX		2012-2016	
Address	City	State	Zip
Diploma/Degree obtained, if any			
BACHELORS OF APPLIES SCIENCE IN HEALTHCARE ADMINISTRATION			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF PHOENIX		09/2024 - 11/03/2025	
Address	City	State	Zip
Diploma/Degree obtained, if any			
MASTERS OF HEALTH ADMINISTRATION			

School Name		From - To (MM/YY – MM/YY	
UNIVERSITY OF PHOENIX		11/2025 - PRESENT	
Address	City	State	Zip
Diploma/Degree obtained, if any			
DOCTORATE IN HEALTHCARE ADMINISTRATION			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016 - 2020	[redacted]	[redacted]	NV	[redacted]
2020-2021			NV	
2021-2023			NV	
2023-2024			NV	
2025			NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: AMADOR MEDICAL			From - To (MM/YY – MM/YY): 02/2011 - PRESENT
Business Address: 4325 DEAN MARTIN DRIVE 340	City: LAS VEGAS	State: NV	Zip: 89103
Phone: 702.724.1734	Title: CARE COORDINATOR		Number of Employed Hours: 30K
Description of Duties: DME SUPPLIES			

Business Name: COLLISION BAY			From - To (MM/YY – MM/YY): 04/2013 - PRESENT
Business Address: 3200 MEADE AVE STE A	City: LAS VEGAS	State: NV	Zip: 89102
Phone: 702.654.6830	Title: ADMINISTRATOR		Number of Employed Hours: 28K
Description of Duties: VEHICLE REPAIR AND MAINTANENCE			

Business Name: COMMUNITY BUSINESS SOLUTIONS			From - To (MM/YY – MM/YY):
Business Address: 7240 DICENTRA RD	City: LAS VEGAS	State: NV	Zip: 89113
Phone: 7255772233	Title: CUNSULTANT		Number of Employed Hours: 0
Description of Duties: CREDENTIALING AND COMPLIANCE CONSULTING FIRM			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2/24/24		NV	PAHRUMP	NYE
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
24TR00443		PAHRUMP JUSTICE COURT		
Reason/Charge				
FIRST DUI				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
ANDRINA VASQUEZ-SANCHEZ				
Name of Business/Industry/Entity				

Provide explanation below:

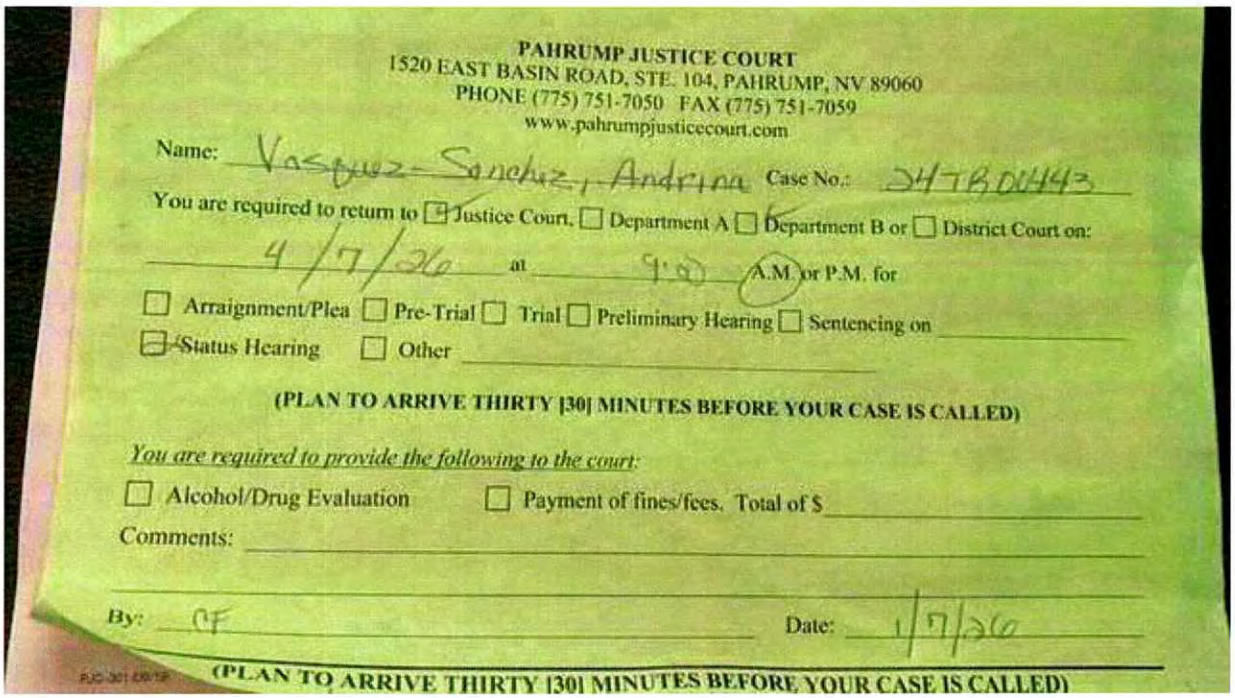
I AM IN THE PROCESS OF COURT FOR AN ARREST ON 2/14/24 FOR DUI MY NEXT COURT DATE IS 1/7/2026

Andrina Vasquez

Original Signature (electronic copies or stamps not accepted)

~~09/22/2025~~ 12/31/25

Date



PAHRUMP JUSTICE COURT
1520 EAST BASIN ROAD, STE. 104, PAHRUMP, NV 89060
PHONE (775) 751-7050 FAX (775) 751-7059
www.pahrumpjusticecourt.com

Name: Vasquez-Sanchez, Andrina Case No.: 24TR00443

You are required to return to ☒ Justice Court, ☐ Department A ☐ Department B or ☐ District Court on:

4/7/26 at 9:00 A.M. or P.M. for

☐ Arraignment/Plea ☐ Pre-Trial ☐ Trial ☐ Preliminary Hearing ☐ Sentencing on _____

☒ Status Hearing ☐ Other _____

(PLAN TO ARRIVE THIRTY [30] MINUTES BEFORE YOUR CASE IS CALLED)

You are required to provide the following to the court:

☐ Alcohol/Drug Evaluation ☐ Payment of fines/fees. Total of $ _____

Comments: _____

By: CF Date: 1/7/26

PJC 301 09/19 **(PLAN TO ARRIVE THIRTY [30] MINUTES BEFORE YOUR CASE IS CALLED)**

I, ANDRINA VASQUEZ-SANCHEZ, **certify that as the MDEG Administrator for**

THE RE-HABIT WELLNESS CASTLE,

that I (initial that you have read and meet the following requirements):

1. AVS Have a high school diploma or its equivalent;
2. AVS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AVS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AVS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANDRINA VASQUEZ SANCHEZ
Print Name (First, Last)

Andrina Vasquez
Original Signature (electronic, copies or stamps not accepted)

10/21/2025
Date

Board Use Only	Date Received:

Kristy Langston

From: Re-Habit Wellness, Inc <rehabitwellnessinc@gmail.com>
Sent: Tuesday, January 13, 2026 8:51 PM
To: Kristy Langston
Subject: Re: MDEG Application - The Re-Habit Wellness Castle

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Please find attached CEU classes that I have taken in the past year to give example of what I work on in DME as I was the person that created forms and documents to assist with the patient all types of medical equipment supplies from hospital beds to power wheelchairs, catheters, bracing, incontinence supplies etc, I was a compliance officer and wrote and read all manuals to operate as well as accreditation and other licencing required to establish a DMEPOS and this has been my dream for 20 years and my legacy. I really enjoy helping people.

BILL109 - Manual Wheelchairs - Documentation and Billing Certification.pdf

BILL109 - Manual Wheelchairs - Documentation and Billing Course Hard Copy .pdf

BILL110 - Power Mobility Devices - Understanding the Process - Certificate.pdf

BILL110 Power Mobility Devices - Understanding the Process Course Hard Copy.pdf

BILL111 - Billing for Repairs and or Replacements.pdf

BILL113a - Hospital Beds Documentation and Billing.pdf

BILL115 - Urological Supplies Documentation and Billing.pdf


BUS015a - Avoiding Fraud and Forgery - Part 1.pdf


BUS015b - Avoiding Fraud and Forgery - Part 2.pdf


BUS015c - Avoiding Fraud and Forgery - Part 3.pdf


BUS017 - MLN Training - Combating Medicare Parts C and D Fraud Waste and Abuse Web-Based Training...


BUS018 - Business Ethics.pdf


BUS018-ML - Business Ethics - 0.25 HR.pdf


BUS021 - MLN Training - Medicare Parts C and D General Compliance.pdf


Code of Ethics.pdf


Compliance Team Education Guide.pdf


Dear Physician - PMD Letter.pdf


DOCUMENTATION CHECKLIST FOR MANUAL WHEELCHAIRS.pdf


Environmental Assessment for Mobility Equipment.doc


HIP001 - Understanding HIPAA.pdf


HIP001-ML - Understanding HIPAA (0.25 HR).pdf

HIP002 - Working with HIPAA.pdf

HIP003 - Managing HIPAA.pdf

Hospital Beds Documentation and Billing.pdf

HQAA Annual Training Requirements.pdf

HR016 - Patient Rights and Responsibilities.pdf

HR016-ML - Patient Rights and Responsibilities - 0.25 HR.pdf

INF002 - Standard Precautions and Infection Control.pdf

INF002-ML - Standard Precautions and Infection Control (0.25 HR).pdf

INF003 - Health Care Workers and Bloodborne Pathogens.pdf

INF003-ML - Health Care Workers and Bloodborne Pathogens (0.25).pdf

INF004 - Occupational Health and Industrial Hygiene.pdf

MANUAL WHEELCHAIR BASES.pdf

There are more but the files are large so I did not want to overload you. Please let me know If this suffices, Thank you

On Tue, Jan 13, 2026 at 8:32 PM Re-Habit Wellness, Inc <rehabitwellnessinc@gmail.com> wrote:

Understood! Thank you for the clarification. I will get working on this for you immediately.

On Tue, Jan 13, 2026 at 11:01 AM Kristy Langston <klangston@pharmacy.nv.gov> wrote:

Hi Andrina,

Please see my responses below in red font.

Thank you,

Kristy Langston

Licensing Supervisor

Nevada State Board of Pharmacy

(775) 850-1440 xt 131

klangston@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site THE RE-HABIT WELLNESS CASTLE

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 621 S 10TH ST

City LAS VEGAS State NV Zip 89101

Mailing Address (if different from physical address) 621 S 10TH ST

City LAS VEGAS State NV Zip 89101

Telephone 725.577.2233 Website N/A

Licensing Company Email REHABITWELLNESSINC@GMAIL.COM

Section 2: Personal Information

First ANDRINA Middle MARIE Last VASQUEZ-SANCHEZ

Alias(es, nicknames, name changes, etc.) PACHECO

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City [redacted] State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: UNIVERSITY OF PHOENIX			From - To (MM/YY – MM/YY): 11/2025- PRESENT
Address	City	State	Zip
Diploma/Degree obtained, if any: DOCTORATE OF SCIENCE IN HEALTHCARE ADMINISTRATION			
School Name: UNIVERSITY OF PHOENIX			From - To (MM/YY – MM/YY): 9/2024-11/2025
Address	City	State	Zip
Diploma/Degree obtained, if any: MASTERS OF SCIENCE IN HEALTHCARE ADMINISTRATION			
School Name: UNIVERSITY OF PHOENIX			From - To (MM/YY – MM/YY): 2012-2016
Address	City	State	Zip
Diploma/Degree obtained, if any: BACHELOR OF SCIENCE IN HEALTHCARE ADMINISTRATION			
School Name: HIGH TECH INSTITUTE			From - To (MM/YY – MM/YY): 2006-2008
Address	City	State	Zip
Diploma/Degree obtained, if any: ASSOCIATES DEGREE OF APPLIES SCIENCE IN SURGICAL TECHNOLOGY			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2016-2020	[redacted]	[redacted]	NV	[redacted]
2020-2021			NV	
2021-2023			NV	
2024-2025			NV	
2025-2026			NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AMADOR MEDICAL LLC			2011-2026
Business Address	**City**	**State**	**Zip**
4325 DEAN MARTIN DRIVE #340,	LAS VEGAS	NV	89103
Phone	**Title**		
702.724.1734	CARE COORDINATOR MEDICAL EQUIPMENT		
Description of Duties			
MEDICAL EQUIPMENT FOR PATIENTS			

Business Name			From - To (MM/YY – MM/YY)
COLLISION BAY			2013-2026
Business Address	**City**	**State**	**Zip**
3200 MEADE AVE STE A	LAS VEGAS	NV	89113
Phone	**Title**		
702.654.6830	ADMINISTRATOR		
Description of Duties			
VEHICLE REPAIR AND MAITENANCE Administration and Credentials			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/14/2024		NV	PAHRUMP	NYE
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
24TR00443		PAHRUMP JUSTICE COURT		
Reason/Charge				
1ST DUI				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
ANDRINA VASQUEZ SANCHEZ				
Name of Business/Industry/Entity				

Provide explanation below:

I WAS ARRESTED FOR DUI AND AM CURRENTLY GOING THROUGH COURT PROCEDINGS AND HAVE NOT BEEN ~~CHARGED~~ - NEXT COURT DATE IS 01/07/2026 WHICH I WILL BE ATTENDING WITH MY ATTORNEY

Convicted
- AVS

Original Signature (electronic, copies or stamps not accepted)

10/01/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANDRINA MARIE VASQUEZ-SANCHEZ

Print Name (First, Last)

Andrina Vasquez-S

Original Signature (electronic, copies or stamps not accepted)

10/01/2025

Date

12/31/25 AVS

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Andrina M Vasquez-Sanchez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Andrina M Vasquez-S

Original Signature

12/31/25

Date

State of Nevada
County of Clark

Subscribed and Sworn to before me this 31st day of December, 2025

J. Liaos

Notary Public Signature

JIM LIAOS
Notary Public
State of Nevada
Appt. No. 07-1102-1
My Appt. Expires December 30, 2026

(Seal)

AVS

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: Not applied Yet
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Arise Pharmacy

Physical Address: 3399 S Eastern Avenue #B

City: Las Vegas State: NV Zip: 89169

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725-735-6904 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725 735-6907 Contact Email: Arisepharmacynv@gmail.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Modupe Ivowoye

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 17933

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Mohye Ivanobeje	NV Pharmacist Registration #: 17933
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Arise Pharmacy LLC

Parent Company (if any): _____

Corporation/Organization Name: Arise Pharmacy LLC

Mailing Address: 3399 S Eastern Ave U #B

City: Las Vegas State: NV Zip: 89169

Telephone: 725-735 6904 Email: _____

Contact Person Name: Moe Irorobeje

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Arise Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

MODUPE IKOROBEJE

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/6/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Modupe Irorobeje hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist (title) for Arise Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of January, 2026

Notary Public

JENNIFER ASHLEY DELGADO
Notary Public, State of Nevada
No. 22-8859-01
My Appt. Exp. Aug. 23, 2026

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Modupe Irorobeje Pharmacist Registration #: 17-933

Pharmacy Name: Arise Pharmacy

Initial each statement below to indicate you have read and agree with the following:

MI I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

MI I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

MI I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

MI I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

MI I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MIrorobeje 1/6/2026

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Modupe Imonbeje

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Mmonbeje

Original signature of Authorized Person (copies or stamps not accepted)

1/6/2026

Date

Board Use Only	Date Received: 1/15/26	Amount: $200.00

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Arise Pharmacy LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/09/2026, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 01/09/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601096409859
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Arise Pharmacy LLC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 3399 S Eastern Avenue #B

City: Las Vegas State: NV Zip: 89169

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 725-735-6904 Website:

Licensing Company Email: Arisepharmacynv@gmail.com

Section 2: Personal Information

First: Modupe Middle: Ajoke Last: Irorobeje

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
Roseman College of Health Sciences	11 Sunset Way	Henderson	NV	89014	08/2007 – 05/2010	Pharm D
Florida Memorial College	15800 NW 42nd Avenue	Miami Gardens	FL	33054	05/2003 – 04/2007	BSc Biology
Northern Kentucky University	99 Nunn Drive	Highland Heights	KY	41099	01/2003 – 05/2003	
Maryland Comprehensive Secondary Sch	2 Ikorodu Rd Mende Maryland	Lagos, Nigeria	Lagos	Nigeria	01/1991 – 12/1997	High School Diploma
					From - To (MM/YY – MM/YY)	
Address		City	State	Zip		Diploma/Degree obtained, if any

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2017 – Present	[redacted]			
05/2014 – 12/2017				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Total Care Medical Consultants			From - To (MM/YY – MM/YY): 01/2021 – Present
Business Address: 3299 S Eastern Avenue	City: Las Vegas	State: NV	Zip: 89169
Phone: 702-444-0438	Title: Clinical Operations Manager		
Description of Duties: Oversight of Clinical operations & patient workflow Cordination of Medication management.			

Business Name: Elevance Health			From - To (MM/YY – MM/YY): 10/2020 – 12/2024
Business Address: 740 W Peachtree St	City: Atlanta	State: GA	Zip: 30308
Phone: 1866-777-9636	Title: Clinical Pharmacy Consultant.		
Description of Duties: Clinical Pharmacy / MTM			

Business Name: Montevista Hospital			From - To (MM/YY – MM/YY): 05/2018 – 05/2020
Business Address: 5900 W Rochelle Ave	City: Las Vegas	State: NV	Zip: 89103
Phone: Closed	Title: Director of Pharmacy		
Description of Duties: Overseeing all Pharmacy Operations Cordination of all pharmacy medication dispensing			

Business Name: Providence Pharmacy			From - To (MM/YY – MM/YY): 08/2013 – 02/2019
Business Address: 1729 E Charleston Blvd	City: Las Vegas	State: NV	Zip: 89104
Phone: Closed	Title: Pharmacy Manager		
Description of Duties: Oversee all Pharmacy Operations			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MODUPE IROROBEJE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Modupe Irorobeje, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/13/2026

Date

Subscribed and Sworn to before me this 13th day of January.

Notary Public Signature

JENNIFER ASHLEY DELGADO
Notary Public, State of Nevada
No. 22-8859-01
My Appt. Exp. Aug. 23, 2026

(Seal)

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FC3841776
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04563		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Capital Care Pharmacy LLC

Physical Address: 5693 S Jones blvd. Ste 119

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-844-8445 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-780-5990 Contact Email: capitalcare702@gmail.com

Website: www.capitalcarepharmacy.com

Nevada Business License # (if applicable) NV20232769499

Supervising/Managing Pharmacist Name (NRS 639.220): Kimberly A. Astorino

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 11536

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kimberly A. Astorino	NV Pharmacist Registration #: 11536
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NA

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Mark Kristoffer Yu

Business Name: Capital Care Pharmacy LLC

Business Address: 5693 S. Jones Blvd. Ste 119

City: Las Vegas State: NV Zip: 89118

Telephone: 702-844-8445 Email: capitalcare702@gmail.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Capital Care Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Mark Kristoffer Yu

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/06/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Mark Kristoffer Yu hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for Capital Care Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 7th day of JANUARY, 20 26

Notary Public

THOMAS C. ENGLUND
Notary Public, State of Nevada
No. 00-39982-1
My Appt. Exp. March 11, 2029

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Kimberly A. Astorino Pharmacist Registration #: 11563

Pharmacy Name: Capital Care Pharmacy LLC

Initial each statement below to indicate you have read and agree with the following:

KA I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

KA I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

KA I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

KA I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

KA I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Stipulation and Order	NV	10/21/2021	18-051-RPH-S

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

01/06/2026
Date

FILED
OCT 15 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KIMBERLY A. ASTORINO, RPH,** **Certificate of Registration No. 11536,** **Respondent.**	**CASE NO. 18-051-RPH-S** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Kimberly A. Astorino, RPh, Certificate of Registration No. 11536, by and through counsel, Kathleen M. Jones, Esq., and Kevin C. Murphy, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent and this matter.

2. On or about July 23, 2021, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. On or about August 6, 2021, Respondent filed an Answer and Notice of Defense to the Accusation.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*, that Respondent violated 21 U.S.C. § 331, 21 U.S.C. § 351, NRS 585.370, NRS 585.520(1) and/or NRS 639.282(1)(d), and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), when she directed a pharmaceutical technician to reconstitute medication for a prescription with an open and partially-consumed bottle of drinking water.

8. Those violations are plead with particularity in the Accusation and are grounds for action pursuant to NAC 639.252(2), NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Kimberly A. Astorino, RPh, Certificate of Registration No. 11536, stipulate to the following penalties:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding her duties and responsibilities as a pharmacist;

B. Respondent shall pay a fine of One Thousand Dollars ($1000.00) for the violations, payable by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985

Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521; within thirty (30) days of the effective date of this Order;

C. Respondent shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order; and

D. Respondent shall complete two (2) extra hours of continuing education (CE) on supervising pharmaceutical technicians, and two (2) extra hours of CE on nonsterile compounding that includes medication reconstitution, in addition to the CE hours she must otherwise complete to maintain licensure. Respondent must provide certificates demonstrating that she completed those additional CEs within sixty (60) days of the effective date of this Order.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing that Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 13, 2021. Respondent may appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330, and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this __ day of October, 2021

KIMBERLY A. ASTORINO, RPH,
Certificate of Registration No. 11536

Signed this 11 day of October, 2021

BRETT [illegible]T, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 7 day of October, 2021

KATHLEEN M. JONES, ESQ.
KEVIN C. MURPHY, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Kimberly A. Astorino, RPh, Certificate of Registration No. 11536, in Case No. 18-051-RPH-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 13th day of October, 2021.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 15th day of October, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Kathleen M. Jones, Esq.
Kevin C. Murphy, Esq.
Murphy Jones APC
5575 Lake Park Way, Suite 218
La Mesa, CA 91942

KRISTOPHER MANGOSING

FILED
JUL 23 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. KIMBERLY A. ASTORINO, RPH, Certificate of Registration No. 11536, Respondent.	CASE NO. 18-051-RPH-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Kimberly A. Astorino, RPH, Certificate of Registration No. 11536, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. Respondent was employed by Sam's Club Pharmacy #10-8177, License No. PH01488, located at 5101 S Pecos Road in Las Vegas, at the time of the events alleged herein.

3. On May 21, 2018, a prescription for amoxicillin 250mg/5ml oral suspension for infant patient R.S. was submitted to Sam's Club Pharmacy #10-8177. The computer system designated the prescription as no. 6930096.

4. Respondent directed Crystal Ledesma, PT, Certificate of Registration No. PT15232, to reconstitute the medication for prescription no. 6930096 with an open and partially-consumed bottle of drinking water.

5. Sam's Club Pharmacy #10-8177 dispensed prescription no. 6930096 on May 22, 2018.

6. Pharmaceutical technician Ledesma reported the incident to the managing pharmacist. After the subsequent investigation produced evidence of Respondent's misconduct and Respondent admitted to her misconduct, Sam's Club Pharmacy #10-8177 terminated Respondent's employment on June 7, 2018.

FIRST CAUSE OF ACTION
Dispensing Adulterated Pharmaceutical Preparation

7. It is unlawful for any person to sell or dispense any pharmaceutical preparation or drug which is adulterated. 21 U.S.C. § 331; 21 U.S.C. § 351; NRS 585.370; NRS 585.520(1); NRS 639.282(1)(d). Additionally, NAC 639.252 states in relevant part:

> If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, ***the pharmacist supervising the pharmaceutical technician*** is responsible for the filled prescription, including, but not limited to, verifying:
> (a) The selection and strength of the drug;
> (b) The dosage form; and
> (c) The labeling of the prescription.

NAC 639.252(2) (emphasis added.).

8. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

9. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

10. Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 331, 21 U.S.C. § 351, NRS 585.370, NRS 585.520(1) and/or NRS 639.282(1)(d) when she directed pharmaceutical technician Ledesma to reconstitute the medication for prescription no. 6930096 with an open and partially-consumed bottle of drinking water. Respondent is therefore subject to discipline pursuant to NAC 639.252(2) and NRS 639.210(11) and (12).

SECOND CAUSE OF ACTION

Unprofessional Conduct

11. Failing to strictly follow the instructions of a practitioner when filling, labeling, and dispensing a prescription constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and is grounds for suspension or revocation of any registration issued by the Board. NRS 639.210(4).

12. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

13. Respondent engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she directed pharmaceutical technician Ledesma to reconstitute the medication for prescription no. 6930096 with an open and partially-consumed bottle of drinking water. Respondent is therefore subject to discipline pursuant to NAC 639.252(2) and NRS 639.210(4).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of this respondent.

DATED this 19th day of July, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. KIMBERLY A. ASTORINO, RPH, Certificate of Registration No. 11536, Respondent.	CASE NO. 18-051-RPH-S STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I:

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway—Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III:

The Board has scheduled your hearing on this matter for Wednesday, September 1, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency

Directive 044 and AB 253, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23RD day of July, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. KIMBERLY A. ASTORINO, RPH, Certificate of Registration No. 11536, Respondent.	CASE NO. 18-051-RPH-S ANSWER AND NOTICE OF DEFENSE

Respondent above-named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

_____

KIMBERLY A. ASTORINO, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this, 27th day of July, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Kimberly A. Astorino, R.Ph.
[redacted]
Las Vegas,NV, [redacted]

SHIRLEY HUNTING

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Kristoffer Yu

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

01/06/2026

Date

Board Use Only	Date Received: 1/12/26	Amount: $500-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Capital Care Pharmacy LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 04/20/2023, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 01/07/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601076402938
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Capital Care Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable): PH04563

Physical Address: 5693 S. Jones Blvd. Ste 119

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-8448445 Website: www.capitalcarepharmacy.com

Licensing Company Email: capitalcare702@gmail.com

Section 2: Personal Information

First: Mark Kristoffer Middle: C Last: Yu

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Beda College		06/98 - 03-02	
Address	**City**	**State**	**Zip**
638 Mendiola St	Manila	NCR	1005
Diploma/Degree obtained, if any			
BSC in Computer Application and Information Science			

School Name		From - To (MM/YY – MM/YY)	
Aquinas School		06/94 - 03/98	
Address	**City**	**State**	**Zip**
183 F. Bluementritt St.	San Juan	NCR	1500
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Holy Angels Montessori School		06/88 - 03/94	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]
06/25 - Present	
06/21 - 06/25	
01/18 - 06/21	
07/17 - 01/18	
03/17 - 07/17	
01/15 - 03/17	

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Capital Care Pharmacy LLC			02/24 - Present	
Business Address		**City**	**State**	**Zip**
5693 S. Jones Blvd. Ste 119		Las Vegas	NV	89118
Phone	**Title**		**Number of Employed Hours**	
702-844-8445	Manager/ Technician		1,600	
Description of Duties				
Oversee all aspect of the pharmacy operations not limited to insurance contracts, reconcillation, HR duties, marketing, scheduling, purchasing, delivery management.				

Business Name			From - To (MM/YY – MM/YY)	
Trinity Pharmacy LLC			1/18 - 04/23	
Business Address		**City**	**State**	**Zip**
2797 S Maryland Pkwy Ste 28		Las Vegas	NV	89109
Phone	**Title**		**Number of Employed Hours**	
702-776-8210	Pharmacy Manager/ Admin Manager		11,266	
Description of Duties				
Oversee all aspect of the pharmacy operations including managing the pharmacy staff, monitoring inventory levels and maintaining complieance with all applicable laws and regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Mark Kristoffer Yu, **certify that as the designated representative for**

Capital Care Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MY I am at least 21 years of age;
3. MY I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MY I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MY I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MY I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MY I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mark Kristoffer Yu

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/06/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Kristoffer Yu

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/07/2026

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, MARK KRISTOFFER YU, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/07/2026

Date

Subscribed and Sworn to before me this 7th day of JANUARY 2026

Notary Public Signature

THOMAS C. ENGLUND
Notary Public, State of Nevada
No. 00-39982-1
My Appt. Exp. March 11, 2029

(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC3841776	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-22-2024

CAPITAL CARE PHARMACY LLC
5693 S JONES BLVD STE 119
LAS VEGAS, NV 891181967

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC3841776	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-22-2024

CAPITAL CARE PHARMACY LLC
5693 S JONES BLVD STE 119
LAS VEGAS, NV 891181967

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC3841776	08-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	02-22-2024

CAPITAL CARE PHARMACY LLC
5693 S JONES BLVD STE 119
LAS VEGAS, NV 891181967

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

U.S. Department of Justice
REPORT CHANGES PROMPTLY
Drug Enforcement Administration

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Capital Care Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04563

Physical Address: 5693 S Jones Blvd Ste 119

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-844-8445 Website: www.capitalcarepharmacy.com

Licensing Company Email: capitalcare702@gmail.com

Section 2: Personal Information

First: Mark Kristoffer Middle: C Last: Yu

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
San Beda College			06/98 - 03/02	
Address		City	State	Zip
638 Mendiola St		Manila	NCR	1005
Diploma/Degree obtained, if any				
BSC in Computer Application & Information Science				
School Name			From - To (MM/YY – MM/YY)	
Aquinas School			06/94 - 03/98	
Address		City	State	Zip
183 F. Blumentritt st		San Juan	NCR	1500
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Holy Angel Montessori School			06/88 - 03/94	
Address		City	State	Zip
83 A. De Legaspi St		Quezon City	NCR	1800
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/25 - Present	[redacted]			
06/21 - 06/25				
01/18 - 6/21				
01/18 - 06/21				
03/17 - 07/17				
01/15 - 03/17				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Capital Care Pharmacy LLC			02/24 - Present	
Business Address	**City**	**State**	**Zip**	
5693 S Jones Blvd Ste 119	Las Vegas	NV	89118	
Phone	**Title**			
702-844-8445	Managing Member			
Description of Duties				
Oversee all aspect of the pharmacy operations not limited to insurance contracts, reconcillation, HR duties, marketing, scheduling, purchasing, delivery management.				

Business Name			From - To (MM/YY – MM/YY)	
Trinity Pharmacy LLC			01/18 - 04/23	
Business Address	**City**	**State**	**Zip**	
2797 S Maryland Pkwy Ste 28	Las Vegas	NV	89109	
Phone	**Title**			
702-776-8210	Manager / Admin Mgr			
Description of Duties				
Oversee all aspect of the pharmacy operations including managing the pharmacy staff, monitoring inventory levels and maintaining complieance with all applicable laws and regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Sony South Africa PTY LTD			07/13 - 12/14	
Business Address	**City**	**State**	**Zip**	
42 Lebombo Rd, Ashlea Gardens	Pretoria	GAU	0081	
Phone	**Title**			
27832551007	Assistant Director			
Description of Duties				
In-Charge of Retail Management Dept, Project Management and Marketing Communications for Sony South Africa.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Kristoffer Yu

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/07/2024

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, MARK KRISTOFFER YU, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/07/2024

Date

Subscribed and Sworn to before me this 7th day of JANUARY 2024

Notary Public Signature

THOMAS C. ENGLUND
Notary Public, State of Nevada
No. 00-39982-1
My Appt. Exp. March 11, 2029

(Seal)

8C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☒ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 03947		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Community Reach Pharmacy

Physical Address: 2610 S Jones Blvd Ste 3

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: (702) 213-3102 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-940-7580 Contact Email: office@sdrxs.com

Website: N/A

Nevada Business License # (if applicable) NV20263510480

Supervising/Managing Pharmacist Name (NRS 639.220): Vinodkumar Gadley

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 09951

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Vinodkumar Gadley	NV Pharmacist Registration #: 09951
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: n/a

Parent Company (if any): n/a

Corporation Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Date of SEC Registration: n/a	SEC Registration Number: n/a	Stock Exchange Symbol: n/a

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): None

Corporation/Organization Name: Community Reach Pharmacy, LLC

Mailing Address: 2085 Saratoga St. Unit A

City: Las Vegas State: NV Zip: 89146

Telephone: 619-738-4311 Email: office@sdrxs.com

Contact Person Name: Alexandre Bagdassarian

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: n/a

Business Name: n/a

Business Address: n/a

City: n/a State: n/a Zip: n/a.

Telephone: n/a Email: n/a

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Community Reach Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Alexandre Bagdassarian

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/15/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Alexandre Bagdassarian hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager (title) for Community Reach Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

STATE- NEVADA
County- CLARK

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15 day of JANUARY, 2026

Notary Public

GREGORY PATER
Notary Public - State of Nevada
County of Clark
APPT. NO. 22-4196-01
My Appt. Expires: November 4, 2026

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Vinodkumar Gadley Pharmacist Registration #: 09951

Pharmacy Name: Community Reach Pharmacy, LLC

Initial each statement below to indicate you have read and agree with the following:

VG I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

VG I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

VG I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

VG I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

VG I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vinodkumar D. Gadley

Original signature of Managing Pharmacist (copies or stamps not accepted)

01/15/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexandre Bagdassarian

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

01/15/2026

Date

Board Use Only	Date Received: 1/20/26	Amount: $500-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Community Reach Pharmacy, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/14/2026, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 01/14/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601146418807
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Community Reach Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable) n/a

Physical Address 2610 S Jones Blvd Ste 3

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) 2085 Saratoga St Unit A

City Las Vegas State NV Zip 89146

Telephone (702) 213-3102 Website tbd

Licensing Company Email office@sdrxs.com

Section 2: Personal Information

First Vinodkumar Middle _____ Last Gadley

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telepho[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Bombay School of Pharmacy.		06/1970 - 06/1975	
Address	City	State	Zip
	Mumbai, India.		
Diploma/Degree obtained, if any			
Bachelors in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Elphinston College.		06/1968 - 06/1970.	
Address	City	State	Zip
	Mumbai, India.		
Diploma/Degree obtained, if any			
Undergraduate Degree.			

School Name		From - To (MM/YY – MM/YY)	
Premier High School.		06/1957 - 06/1968	
Address	City	State	Zip
	Mumbai, India.		
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
n/a			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
n/a			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2019 - Current	[redacted]			
01/2016 - 12/31/20				
01/2005 - 12/31/20				
n/a				
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Goodwill Pharmacy				
Business Address		**City**	**State**	**Zip**
2610 S Jones Blvd Ste 3		Las Vegas	NV	89146
Phone	**Title**		**Number of Employed Hours**	
(702) 213-3102	Pharmacist in Charge			
Description of Duties				
Dispensing prescription drugs, inventory control, compliance with state and federal pharmacy laws, recordkeeping, supervision of pharmacy staff.				

Business Name			From - To (MM/YY – MM/YY)	
Empire Pharmacy Consultants.			01/2017 - 06/2025	
Business Address		**City**	**State**	**Zip**
936 SW 1st Ave		Miami	FL	33130
Phone	**Title**		**Number of Employed Hours**	
855-374-1029	Pharmacist		10,000 hrs.	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Vinodkumar Gadley, **certify that as the designated representative for**

Community Reach Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VG I am at least 21 years of age;
3. VG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Vinodkumar Gadley

Print Name (First, Last)

Vinodkumar Gadley

Original Signature (electronic, copies or stamps not accepted)

01/15/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vinodkumar Gadley

Print Name (First, Last)

Vinodkumar N Gadley

Original Signature (electronic, copies or stamps not accepted)

1/15/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Vinodkumar N Gadley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Vinodkumar N Gadley

Original Signature

1/15/2026

Date

Subscribed and Sworn to before me this 15 day of January 2026.

Ashley Brown Webb

Notary Public Signature

ASHLEY BROWN WEBB
Notary Public - State of Nevada
Appointment Recorded in Clark County
No: 22-4387-01 - Expires June 10, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Community Reach Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): n/a

Physical Address: 2610 S Jones Blvd Ste 3

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: (702) 213-3102 Website: n/a

Licensing Company Email: office@sdrxs.com

Section 2: Personal Information

First: Alexandre Middle: Last: Bagdassarian

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Henrico High School			09/91 - 06/95	
Address	**City**		**State**	**Zip**
302 Azalea Ave	Henrico		VA	23227
Diploma/Degree obtained, if any				
High School Diploma				

School Name			From - To (MM/YY – MM/YY)	
n/a				
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
n/a				
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
n/a				
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
n/a				
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/26 - Present	[redacted]			
05/21 - Present				
08/05 - 04/21				
n/a				
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Pacific Diagnostics, Inc.			06/20 - Present
Business Address	**City**	**State**	**Zip**
15725 Pomerado Rd	Poway	CA	92064
Phone	**Title**		
619-738-4311	President		

Description of Duties

Provided executive leadership and business management, including strategic planning, financial oversight, and regulatory compliance. Coordinated with licensed professionals and external vendors.

Business Name			From - To (MM/YY – MM/YY)
Clean Cosmetics			08/14 - 05/20
Business Address	**City**	**State**	**Zip**
9811 Owensmouth Ave Ste 6	Chatsworth	CA	91311
Phone	**Title**		
818-678-9760	Operations		

Description of Duties

Led operational management of a cosmetics manufacturing company, including production oversight, quality control coordination, vendor management, and regulatory compliance. Oversaw business operations and external partnerships.

Business Name			From - To (MM/YY – MM/YY)
n/a			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
n/a			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
n/a			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexandre Bagdassarian

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-15-2026

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, Alexandre Bagdassarian, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-15-2026

Date

STATE - NEVADA
County - CLARK

Subscribed and Sworn to before me this 15 day of JANUARY, 2026

Notary Public Signature

GREGORY PATER
Notary Public - State of Nevada
County of Clark
APPT. NO. 22-4196-01
My Appt. Expires: November 4, 2026

(Seal)

8D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: LYFE PHARMACY

Physical Address: 9280 W SUNSET RD STE 230

City: LAS VEGAS State: NEVADA Zip: 89148

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-744-9454 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725-205-2625 Contact Email: LYFEPHARMACY23@GMAIL.COM

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): MATHEW EISSA

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23068

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: MATHEW EISSA	NV Pharmacist Registration #: 23068
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): NA

Corporation/Organization Name: VITA PHARMACY

Mailing Address: 9280 W SUNSET RD STE 230

City: LAS VEGAS State: NEVADA Zip: 89148

Telephone: 7027449454 Email: LYFEPHARMACY23@GMAIL.COM

Contact Person Name: MATHEW EISSA

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the OWNER (title) for LYFE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

RAMY MASSOUD

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/15/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, RAMY MASSOUD hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER (title) for LYFE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

STATE OF NEVADA
COUNTY OF CLARK

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of SEPTEMBER, 20 25 by Ramy Massoud.

Notary Public

MERCEDEZ DAVIS
Notary Public, State of Nevada
No. 25-7281-01
My Appt. Exp. June 23, 2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RAMY MASSOUD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

09/15/2025

Date

Board Use Only	Date Received: 11/25/25	Amount: $500.00

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: MATHEW EISSA Pharmacist Registration #: 23068

Pharmacy Name: LYFE PHARMACY

Initial each statement below to indicate you have read and agree with the following:

ME — I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

ME — I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

ME — I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

ME — I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

ME — I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

09/15/2025
Date

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Vita Pharmacy Inc** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/17/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/04/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202602046468077
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE Director:

Name	Country
Ramy Massoud	USA

Address	City	State	Zip/Postal Code
[redacted]	Eastvale	CA	[redacted]

CORPORATION, INDICATE THE President:

Name	Country
Ramy Massoud	USA

Address	City	State	Zip/Postal Code
[redacted]	Eastvale	CA	[redacted]

CORPORATION, INDICATE THE Treasurer:

Name	Country
Ramy Massoud	USA

Address	City	State	Zip/Postal Code
[redacted]	Eastvale	CA	[redacted]

CORPORATION, INDICATE THE Secretary:

Name	Country
Ramy Massoud	USA

Address	City	State	Zip/Postal Code
[redacted]	EASTVALE	CA	[redacted]

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X Ramy Massoud	President	08/27/2025
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*	**Title**	**Date**

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler LYFE PHARMACY

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 9280 W SUNSET RD STE 230

City LAS VEEGAS State NEVADA Zip 89148

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-744-9454 Website N/A

Licensing Company Email LYFEPHARMACY23@GMAIL.COM

Section 2: Personal Information

First MATHEW Middle _____ Last EISSA

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITI[redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

Ci[redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY OF HEALTH SCINECES		07/2019-05/2022	
Address	**City**	**State**	**Zip**
11 SUNSET WAY	HENDERSON	NV	89014
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
NEVADA STATE UNIVERSITY		05/2015-05/2019	
Address	**City**	**State**	**Zip**
1300 NEVADA STATE DR	HENDERSON	NV	89002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
10/2010-PRESENT				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: WALGREENS PHARMACY			From - To (MM/YY – MM/YY): 05/2015-09/2019
Business Address: 6101 W LASKE MEAD BLVD	City: LAS VEGAS	State: NV	Zip: 89119
Phone: 702-648-2732	Title: PHARMCY TECH		Number of Employed Hours: 4808
Description of Duties:			

Business Name: CVS OMNICARE			From - To (MM/YY – MM/YY): 07/2019-09/2022
Business Address: 1525 E SUNSET RD	City: LAS VEGAS	State: NV	Zip: 89119
Phone: 702-407-0124	Title: PHARMACY INTERN/PHARMCIST		Number of Employed Hours: 4080
Description of Duties:			

Business Name: APC Inc. Desert Hope treatment Center			From - To (MM/YY – MM/YY): 10/22 - 7/24
Business Address: 2465 twain ave	City: Las Vegas	State: N.V.	Zip: 89121
Phone: 702-874-3798	Title: pharmacist		Number of Employed Hours: 2,562
Description of Duties:			

Business Name: Saint mary pharmacy			From - To (MM/YY – MM/YY): 11/22 - 12/24
Business Address: 4180 S. Rainbow Blvd	City: Las Vegas	State: N.V.	Zip: 89103
Phone: 702-722-3707	Title: pharmacist		Number of Employed Hours: 3,843
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, MATHEW EISSA, certify that as the designated representative for

LYFE PHARMACY

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ME I am at least 21 years of age;
3. ME I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ME I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ME I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ME I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ME I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

MATHEW EISSA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MATHEW EISSA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/05/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Mathew Eissa, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/5/26

Date

Subscribed and Sworn to before me this 5th day of January, 2026

Notary Public Signature

NATALIA YANEVA PETROVA
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 25-2812-01
MY APPT. EXPIRES MAR. 18, 2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler _____

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address _____

City _____ State _____ Zip _____

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First RAMY Middle _____ Last MASSOUD

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Devery University			96 - 2000	
Address	City		State	Zip
	Long Beach		CA	
Diploma/Degree obtained, if any				
BS Accounting				
School Name			From - To (MM/YY – MM/YY)	
Keller Schole of Mangment			2001 - 2003	
Address	City		State	Zip
	Long Beac		CA	
Diploma/Degree obtained, if any				
MBA				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013 - Now	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)
Gano Excel USA In		2013 - Now

Business Address	City	State	Zip
8652 Kimball Ave	Eastvale	CA	9[illegible]08

Phone	Title

Description of Duties: Director of Accounting and HR

Business Name	From - To (MM/YY – MM/YY)
E & R Pharmacy P.C	2015 - Now

Business Address	City	State	Zip
770 Magnolya Ave unit G	Corona	CA	92879

Phone	Title
	President

Description of Duties: Owner

Business Name	From - To (MM/YY – MM/YY)
Eliana Pharmacy Inc	2024 - Now

Business Address	City	State	Zip
13641 Central Ave unit E	Chino	CA	91710

Phone	Title
	President

Description of Duties: Owner

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

RAMY MASSOUD

Print Name (First, Last)

Ramy Massoud — 10/10/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Harris

I, Ramy Massoud, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ramy Massoud — 10/13/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 13th day of October 2025.
by Ramy Massoud

Shae Gamble

Notary Public Signature

NOTARY PUBLIC STATE OF TEXAS

Shae Gamble

ID NUMBER
13333024-2
COMMISSION EXPIRES
September 14, 2029

(Seal)

Electronically signed and notarized online using the Proof platform.

8E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 04704	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: FN5565760 ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Nevada Care Pharmacy LLC

Physical Address: 3430 E Tropicana Ave Suite 25

City: Las Vegas State: NV Zip: 89121

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7024622259 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 7026654388 Contact Email: nevadacarepharmacy@gmail.com

Website: www.nevadacarepharmacy.com

Nevada Business License # (if applicable) NV20253311620

Supervising/Managing Pharmacist Name (NRS 639.220): Richard D Nguyen

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20757

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Richard D Nguyen	NV Pharmacist Registration #: 20757
Name: Kristina S Kim	NV Pharmacist Registration #: 22482
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Guadalupe Sokol

Business Name: Nevada Care Pharmacy LLC

Business Address: 3430 E Tropicana Ave Suite 25

City: Las Vegas State: NV Zip: 89121

Telephone: 7024622259 Email: nevadacarepharmacy@gmail.com

Section 9: Statement of Responsibility – MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Nevada Care Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Guadalupe Sokol

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

Date 10/25/2025

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Guadalupe Sokol hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for Nevada Care Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of October, 2025

Notary Public

LIUBA CRUZ MACHADO
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 25-7511-01
My Appt. Expires 01/13/2029

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Richard Nguyen Pharmacist Registration #: 20757

Pharmacy Name: Nevada Care Pharmacy LLC

Initial each statement below to indicate you have read and agree with the following:

RN I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

RN I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

RN I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

RN I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

RN I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

10/25/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Guadalupe Sokol

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

10/25/25

Date

Board Use Only	Date Received: 11/20/25	Amount: $500-CC

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

NEVADA CARE PHARMACY LLC

Organizational Documents on File	Filing Date
Articles of Organization	03/12/2025

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence NEVADA CARE PHARMACY LLC, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 03/12/2025, and is in good standing in this state.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Nevada Care Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable) PH04704

Physical Address 3430 E tropicana ave ste 25

City Las Vegas State NV Zip 89121

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702.462.2259 Website nevadacarepharmacy.com

Licensing Company Email nevadacarepharmacy@gmail.com

Section 2: Personal Information

First Richard Middle D Last Nguyen

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] Stat[redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF UTAH COLLEGE OF PHARMACY		08/2015 - 08/19	
Address: 282 2000 E	City: Salt Lake City	State: UT	Zip: 84112
Diploma/Degree obtained, if any: Doctorate of Pharmacy (PharmD.)			

School Name		From - To (MM/YY – MM/YY)	
California State University, Long Beach		08/06 - 12/11	
Address: 1250 Bellflower Blvd	City: Long Beach	State: CA	Zip: 90840
Diploma/Degree obtained, if any: Bachelors of Science, Business Management			

School Name		From - To (MM/YY – MM/YY)	
Fountain Valley High School		08/02 - 05/06	
Address: 17816 Bushard Street	City: Fountain Valley	State: CA	Zip: 92708
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/25 – Present	[redacted]			
05/23 - 03/25				
10/22 - 05/23				
04/21 - 10/22				
09/19 - 04/21				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Nevada Care Pharmacy			
Business Address	**City**	**State**	**Zip**
3430 E Tropicana Avenue Ste 25	Las Vegas	NV	89121
Phone	**Title**	**Number of Employed Hours**	
(702) - 462 - 2259	Pharmacy Manager	128	
Description of Duties	• Maintain pharmacy workflow • counsel pts, answering phone calls • Maintain inventory		

Business Name			From - To (MM/YY – MM/YY)
US Pharmacy			01/25 - Present
Business Address	**City**	**State**	**Zip**
3871 S Valley View Blvd Ste 13	Las Vegas	NV	89103
Phone	**Title**	**Number of Employed Hours**	
(702) 916 - 4622	Staff Pharmacist	754	
Description of Duties	• Maintain pharmacy workflow • counsel pts, answering phone calls		

Business Name			From - To (MM/YY – MM/YY)
Silver State Pharmacy			11/24 - Present
Business Address	**City**	**State**	**Zip**
1591 N Buffalo Dr Ste 140	Las Vegas	NV	89128
Phone	**Title**	**Number of Employed Hours**	
(702) 463 - 3891	Staff Pharmacist	300	
Description of Duties	• Maintain pharmacy workflow • Counsel pts, answering phone calls		

Business Name			From - To (MM/YY – MM/YY)
Advance Pharma			01/24 - 11/24
Business Address	**City**	**State**	**Zip**
5000 W Oakley Boulevard	Las Vegas	NV	89146
Phone	**Title**	**Number of Employed Hours**	
(702) 341 - 9316	Pharmacist Manager	352	
Description of Duties	• Maintained pharmacy workflow • Counseled patients, answering phone calls • Maintain inventory		

Business Name			From - To (MM/YY – MM/YY)
First Class Rx Pharmacy			06/23 - 08/23
Business Address	**City**	**State**	**Zip**
3783 E Desert Inn Rd	Las Vegas	NV	89121
Phone	**Title**	**Number of Employed Hours**	
(702) 534 - 0325	Staff Pharmacist	250	
Description of Duties	• Maintained pharmacy workflow • Counseled patients, answering phone calls		

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Walgreens Pharmacy			03/21 - 10/22
Business Address	**City**	**State**	**Zip**
6820 W Ann Rd	Las Vegas	NV	89130
Phone	**Title**	**Number of Employed Hours**	
(702) 645-4106	Staff Pharmacist	3,120	
Description of Duties	• Maintained pharmacy workflow • Counseled patients; answered phone calls • Administered vaccines		

Business Name			From - To (MM/YY – MM/YY)
Smith's Food & Drugs			05/15 - 08/19
Business Address	**City**	**State**	**Zip**
876 E 8005	Salt Lake City	UT	84102
Phone	**Title**	**Number of Employed Hours**	
(801) 355-2801	Pharmacy Intern	1,250	
Description of Duties	• Dispensed medications • Helped answer phones & counsel patients under pharmacist supervision • Administered vaccines		

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Richard Nguyen, **certify that as the designated representative for**

Nevada Care Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RN ✓ I am at least 21 years of age;
3. RN ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RN ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RN ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RN ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RN ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Richard Nguyen
Print Name (First, Last)

Original Signature (~~electronic~~, copies or stamps not accepted)

11/12/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Nguyen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/12/2025
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Richard Nguyen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/12/2025
Date

Subscribed and Sworn to before me this 12 day of November

Notary Public Signature

Daria Shalina
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 24-3498-01
My Appt. Expires March 15, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Nevada Care Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04704

Physical Address: 3430 E tropicana Ave Suite 25

City: Las Vegas State: NV Zip: 89121

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 7024622259 Website: www.nevadacarepharmacy.com

Licensing Company Email: nevadacarepharmacy@gmail.com

Section 2: Personal Information

First: Guadalupe Middle: Last: Sokol

Alias(es, nicknames, name changes, etc.): De Los Reyes

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Addres: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Guadalupe Sokol

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
26 De Julio HighSchool			08/89-06/93
Address	**City**	**State**	**Zip**
La Habana , Cuba	La Habana	Cuba	n/a
Diploma/Degree obtained, if any			
Highschool Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/19-current	[redacted]			
08/18-08/19				
08/17-08/18				
06/17-08/17				
06/16-06/17				
09/09-06/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Guadalupe Sokol

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Always Your Pharmacy		09/23-03/25	
Business Address	**City**	**State**	**Zip**
821 N Lamb Blvd Ste 5	Las Vegas	NV	89110
Phone	**Title**		
7024622205	Pharmacy Technician		

Description of Duties

Filling medications, Answering Phones, billing, file prescriptions/deliver logs/etc.

Business Name		From - To (MM/YY – MM/YY)	
First Class Rx Pharmacy		11/16-08/23	
Business Address	**City**	**State**	**Zip**
7783 E Desert Inn Rd	Las Vegas	NV	89121
Phone	**Title**		
7025340325	Pharmacy Technician		

Description of Duties

Fill Medications, Billing, answering Phones, File prescription/deliver logs/etc,

Business Name		From - To (MM/YY – MM/YY)	
La Colonia Medical Center		11/10-10/16	
Business Address	**City**	**State**	**Zip**
7235 Corporate Center Dr	Miami	FL	33126
Phone	**Title**		
7868038483	Pharmacy Technician		

Description of Duties

Answering Phones, fill medications, billing, file deliver logs/ prescriptions/etc.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section B: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Guadalupe Sokol

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/25/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Guadalupe Sokol, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/25/25

Date

Subscribed and Sworn to before me this 25 day of October.

Notary Public Signature

LIUBA CRUZ MACHADO
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 25-7511-01
My Appt. Expires 01/13/2029

(Seal)

8F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FQ6034350
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH PH03563		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: QHR PHARMACY 1

Physical Address: 765 N NELLIS BLVD STE 7

City: LAS VEGAS State: NV Zip: 89110

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-331-6388 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-331-7791 Contact Email: qhrnellis@gmail.c

Website: _____

Nevada Business License # (if applicable) PH03563

Supervising/Managing Pharmacist Name (NRS 639.220): EMMA B. SICAM

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): LICENSE#16680

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: EMMA B, SICAM — NV Pharmacist Registration #: 16680

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Name: _____ — NV Pharmacist Registration #: _____

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA — Credentials: NA — %: _____

Name: _____ — Credentials: _____ — %: _____

Name: _____ — Credentials: _____ — %: _____

Name: _____ — Credentials: _____ — %: _____

Name: _____ — Credentials: _____ — %: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: KEVIN CURBELO PRIETO

Business Name: QHR PHARMACY 1

Business Address: 765 N NELLIS BLVD STE 7

City: LAS VEGAS State: NV Zip: 89110

Telephone: 702-331-6388 Email: qhrnellis@gmail.co

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the KEVIN CURBELO PRIETO (title) for OWNER (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

KEVIN CURBELO PRIETO

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/14/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, KEVIN CURBELO PRIETO hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER (title) for QHR PHARMACY 1 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 14 day of January, 20 26.

Notary Public

YANET GARCIA BUERGO
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 22-8850-01
My Appt. Expires June 24, 2026

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: EMMA B, SICAM Pharmacist Registration #: 16680

Pharmacy Name: QHR PHARMACY 1

Initial each statement below to indicate you have read and agree with the following:

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Citation / Discipline	NV	04/17/2013	12-018-RPH-S

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted) Date 01/14/2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Curbelo Prieto

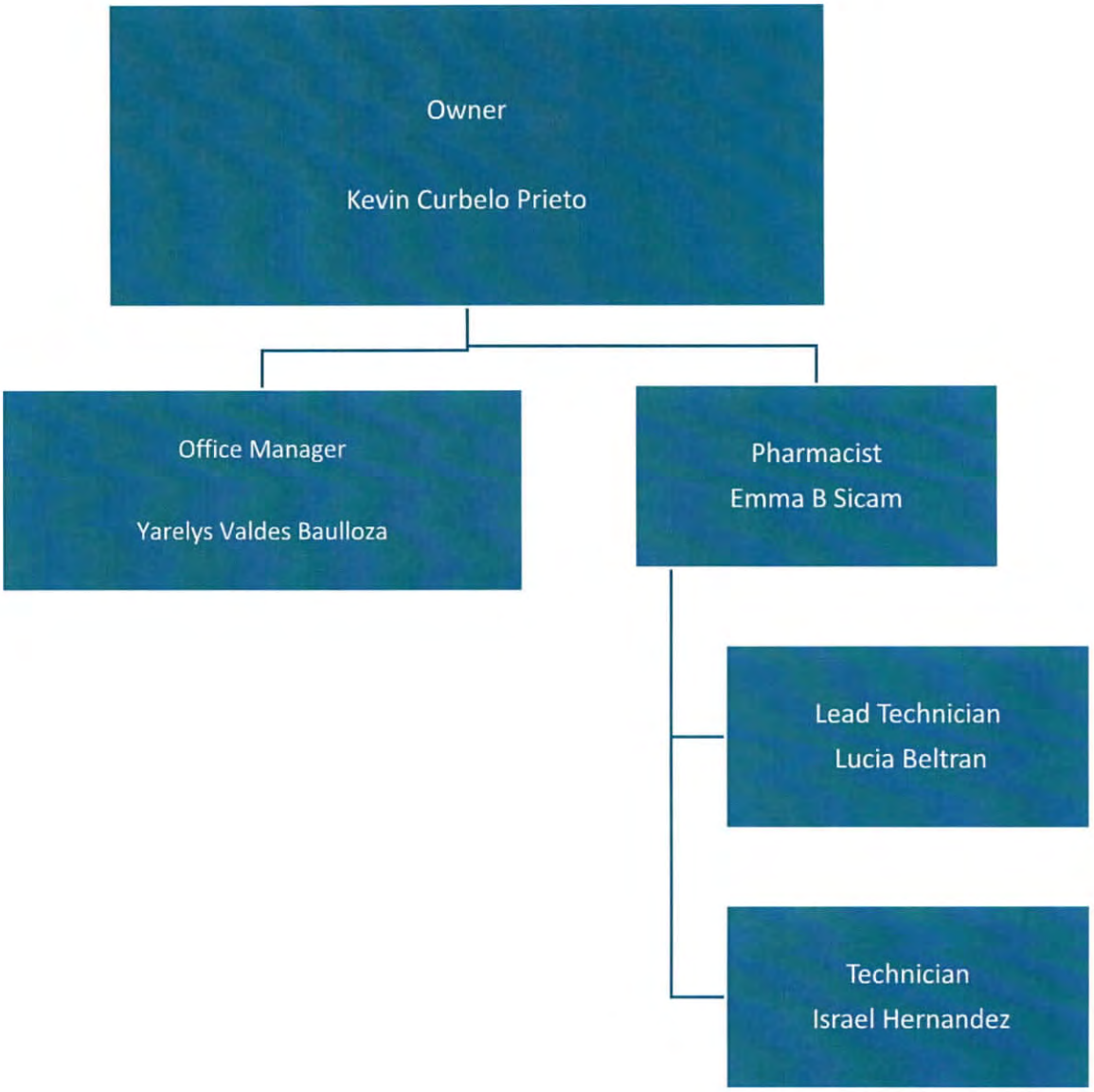
Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/14/26

Date

Board Use Only	Date Received: 1/21/26	Amount: $500 CC


Owner
Kevin Curbelo Prieto
Office Manager
Yarelys Valdes Baulloza
Pharmacist
Emma B Sicam
Lead Technician
Lucia Beltran
Technician
Israel Hernandez

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **QHR PHARMACY 1, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/29/2016, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/12/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202512126352446
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler QHR Pharmacy 1

Pharmacy/Wholesaler License # (if applicable) PH03563

Physical Address 765 Nellis Blvd STE 7

City Las Vegas State NV Zip 89110

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Lucia Middle De los Angeles Last Beltran

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Everest College		2013	
Address	**City**	**State**	**Zip**
300 Six Flags Dr, STE 100	Arlington	TX	76011
Diploma/Degree obtained, if any			
Pharmacy Technician			

School Name		From - To (MM/YY – MM/YY)	
IPVCE Lenin		09/90-07/94	
Address	**City**	**State**	**Zip**
Calle 19 Vedado	La Habana	La Habana	10400
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22-Present	[redacted]			
06/20-2/22				
01/17-6/20				
12/08-01/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
US Pharmacy			2/23-11/25	
Business Address		**City**	**State**	**Zip**
3871 S Valley View Blvd		Las Vegas	NV	89103
Phone	**Title**		**Number of Employed Hours**	
702-916-4622	Pharmacy Tech		5280	
Description of Duties				
Count medication, fill prescription, enter prescriptions in the system, make phone calls and customer service.				

Business Name			From - To (MM/YY – MM/YY)	
First Class Pharmacy RX Pharmacy			10/16-1/23	
Business Address		**City**	**State**	**Zip**
3783 E Dessert Inn Rd		Las Vegas	NV	89121
Phone	**Title**		**Number of Employed Hours**	
702-534-0325	Pharmacy Tech		12,000	
Description of Duties				
Count medication, fill prescription, enter prescriptions in the system, make phone calls and customer service.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Lucia Beltran, **certify that as the designated representative for**

QHR Pharmacy 1,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LB I am at least 21 years of age;
3. LB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lucia Beltran

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/14/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lucia Beltran

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/14/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark.

I, Lucia Beltran, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/14/26

Date

Subscribed and Sworn to before me this 14 day of January, 2026.

Notary Public Signature

YANET GARCIA BUERGO
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 22-8850-01
My Appt. Expires June 24, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site QHR PHARMACY 1

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03563

Physical Address 765 N NELLIS BLVD STE 7

City LAS VEGAS State NEVADA Zip 89110

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-331-6388 Website _____

Licensing Company Email qhrnellis@gmail.com

Section 2: Personal Information

First KEVIN Middle _____ Last CURBELO PRIETO

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Teleph[redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, Berkeley - Haas School of Business		08/25-05/27	
Address	**City**	**State**	**Zip**
2220 Piedmont Avenue	Berkeley	CA	94720
Diploma/Degree obtained, if any			
B.S. Business Administration			

School Name		From - To (MM/YY – MM/YY)	
University of California, Berkeley		08/23-05/25	
Address	**City**	**State**	**Zip**
110 Sproul Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
Economics and Legal Studies			

School Name		From - To (MM/YY – MM/YY)	
Advanced Technologies Academy (A-Tech)		08/19-05/23	
Address	**City**	**State**	**Zip**
1411 Robin Street	Las Vegas	NV	89106
Diploma/Degree obtained, if any			
High School Diploma - High Honors Distinction and Criminal Justice Focus			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/25-Present	[redacted]			
08/24-05/25				
08/23-05/24				
12/19-Present				
05/13-12/19				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Fenwick & West LLP			12/25- Present
Business Address	**City**	**State**	**Zip**
555 California Street	San Francisco	CA	94104
Phone	**Title**		
415-875-2300	Finance Intern (Accounts Payable Group)		

Description of Duties

I am tasked with looking at invoices, reimbursement requests, and different financial control checks that are relating to the accounts payable matters within the finance department. The accounts payable team that I am a part of is a total of 6 members and covers all accounts payable matters across the entire United States.

Business Name			From - To (MM/YY – MM/YY)
San Francisco District Attorney's Office			09/25-12/25
Business Address	**City**	**State**	**Zip**
350 Rhode Island St, North Building, Suite 400N	San Francisco	CA	94103
Phone	**Title**		
628-652-4000	Legal Undergraduate Intern		

Description of Duties

I compiled financial fraud data from over 1,000+ case-file pages and summarized findings for 2 preliminary hearings on medical fraud. I also created an informational deck for a joint event between SFDA and Tiburon DA's office about FD-1 forms, covering auto insurance fraud.

Business Name			From - To (MM/YY – MM/YY)
Cal Athletics			09/25-Present
Business Address	**City**	**State**	**Zip**
Memorial Stadium #4426	Berkeley	CA	94720
Phone	**Title**		
510-642-2427	Event Sales and Operations Intern		

Description of Duties

Managed player-guest check ins by verifying credentials, signing in attendees, and coordinating with game day access staff for 10+ games. Shadowed UCSF Sports Management master's students for 75+ hours, performing control checks and assessing protocol compliance.

Business Name			From - To (MM/YY – MM/YY)
U.S. Securities and Exchange Commission			01/25-05/25
Business Address	**City**	**State**	**Zip**
44 Montgomery St	San Francisco	CA	94104
Phone	**Title**		
415-705-2500	Division of Examinations Intern		

Description of Duties

I conducted compliance examinations of investment advisory firms with $100M+ in AUM to ensure adherence to SEC financial regulations. Throughout this tenure I also shadowed people in the office specializing in cryptocurrency and robo-advisory.

Business Name			From - To (MM/YY – MM/YY)
US Pharmacy			07/22-08/24
Business Address	**City**	**State**	**Zip**
3871 S Valley View Blvd STE 13	Las Vegas	NV	89103
Phone	**Title**		
702-916-4622	Administrative Assistant		

Description of Duties

Worked with wholesales and insurances to ensure contracts and to make sure operations flow smoothly. Worked with staff to make sure that onboarding and company culture is maintained.

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Curbelo Prieto

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/14/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Kevin Curbelo Prieto, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/14/26

Date

Subscribed and Sworn to before me this 14 day of January / 2026.

Notary Public Signature

YANET GARCIA BUERGO
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 22-8850-01
My Appt. Expires June 24, 2026

(Seal)

8G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Pharmacy Location	Application Type	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada ☐ Out-of-Nevada	~~☒ New Pharmacy~~ ~~■ Ownership Change*~~ ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH ~~04648~~ N/A	■ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: pending new permit ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ■ Long Term Care ☐ Hospital ☐ Other:

Amended 2/6/26 MA

Pharmacy Operation (check all applicable boxes)		Ownership Type (check applicable box)
■ Monday ■ Tuesday ■ Wednesday ■ Thursday	■ Friday ☒ Saturday ☐ Sunday ☐ Holidays	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Pharmacy Information

Pharmacy Name: Tera Pharmacy

Physical Address: 8995 W Flamingo Rd

City: Las Vegas State: NV Zip: 89147

Mailing Address (if different from physical address): same

City: same State: same Zip: same

Telephone: 702-780-4144 Toll Free # (NAC 639.708, NRS 639.23286): n/a

Fax: 702-749-3133 Contact Email: stmaryrxlv@gmail.com

Website: n/a

Nevada Business License # (if applicable) NV20091170440101

Supervising/Managing Pharmacist Name (NRS 639.220): Grace Marielle Singson

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24727

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Grace Marielle Singson	NV Pharmacist Registration #: 24727
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company:	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: n/a

Parent Company (if any): n/a

Corporation Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Date of SEC Registration: n/a | SEC Registration Number: n/a | Stock Exchange Symbol: n/a

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): n/a

Corporation/Organization Name: Saint Mary Pharmacy Inc

Mailing Address: 8995 W Flamingo Rd Ste 120

City: Las Vegas State: NV Zip: 89147

Telephone: 702-780-4144 Email: stmaryrxlv@gmail.com

Contact Person Name: Mark Mahfouz

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: n/a

Business Name: n/a

Business Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the officer / owner (title) for Tera Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Mark Magdi Mahfouz

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/25/2025

Date

Section 10: Affidavit for Pharmacies: MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Mark Mahfouz hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the officer / owner (title) for Tera Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of November, 2025

Notary Public

PLEASE SEE THE ATTACHMENT
MM 11/25/2025

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

Signature of Document Signer No. 1

Signature of Document Signer No. 2 (if any)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 25 (*Date*) day of November (*Month*), 2025 (*Year*),
by
(1) Mark Mahfouz

(and ~~(2)~~ _____),
Name(~~s~~) of Signer(~~s~~)

proved to me on the basis of satisfactory evidence to be the person(~~s~~) who appeared before me.

RAMIN MIRAGE
COMM. #2453113
Notary Public - California
Los Angeles County
My Comm. Expires July 13, 2027

Signature _____
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Affidavit For Pharmacy License Document Date: _____

Number of Pages: _____ Signer(s) Other Than Named Above: _____

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Section 11 – Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Grace Marielle Singson Pharmacist Registration #: 24727

Pharmacy Name: Tera Pharmacy

Initial each statement below to indicate you have read and agree with the following:

GS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

GS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

GS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

GS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

GS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
n/a	n/a	n/a	n/a

Criminal Actions:	State:	Date:	Case #:	County:	Court:
n/a	n/a	n/a	n/a	n/a	n/a

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

11/25/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Mahfouz, CEO (officer)

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/25/2025
Date

Board Use Only	Date Received: 11/26/25	Amount: $500 cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **SAINT MARY PHARMACY INC** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/18/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/25/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202511256305382
You may verify this certificate online at https://www.nvsilverflume.gov/home

Saint Mary Pharmacy Inc

Tera Pharmacy

Listing of officers, directors, and stockholders

Mark Mahfouz – Pres / Treasurer / Director and 100% stockholder

Giselle Acosta – Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Tera Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH04648

Physical Address 8995 W. Flamingo Rd. Ste. 120

City Las Vegas State NV Zip 89147

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-780-4144 Website _____

Licensing Company Email Stmarycxlv@gmail.com

Section 2: Personal Information

First Ana Middle Maria Last Lemos

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Rancho High		From - To (MM/YY – MM/YY): 8/95 – 5/99	
Address: 1900 E. Owens Ave	City: N. LV	State: NV	Zip: 89030
Diploma/Degree obtained, if any: Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 1/20 – 1/26	[redacted]			
From - To (MM/YY – MM/YY): 08/19 – 12/19				
From - To (MM/YY – MM/YY): 11/15 – 7/19				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Tera Pharmacy			From - To (MM/YY – MM/YY): 10-25 – Current
Business Address: 8995 W. Flamingo Rd Ste 120	City: LV	State: NV	Zip: 89147
Phone: (702) 780-4144	Title: Pharmacy Tech.	Number of Employed Hours: 570 Hours	
Description of Duties: Prescription Processing, Med Prepping/Dispensing, Patient interaction Inventory management, Admin Tasks, Collaboration w/ Healthcar Professionals, Compliance & safety.			

Business Name: Atlas Pharmacy			From - To (MM/YY – MM/YY): 7/25-10-25
Business Address: 3585 S. Maryland Pkwy	City: LV	State: NV	Zip: 89169
Phone: (725) 205-3641	Title: Lead Pharmacy Tech	Number of Employed Hours: 320 Hours	
Description of Duties: Rx Processing, Med prepping, Med Delivery, Medication Inventory Compliance & safety, Admin tasks.			

Business Name: Credo Pharmacy.			From - To (MM/YY – MM/YY): 12-20 - 3/24
Business Address: 8995 W. Flamingo Rd Ste 120.	City: LV	State: NV	Zip: 89147
Phone: (702) 800-4000	Title: Lead Pharmacy Tech	Number of Employed Hours: 6,782.86	
Description of Duties: Patient interactions, Admin Tasks, Inventory management. Prescription processing, Colab w/ Healthcare Professionals, compliance & safety.			

Business Name: Rawson-Neal SNAMHS.			From - To (MM/YY – MM/YY): 1/99 - 11/2015
Business Address: 1650 Community College Dr.	City: LV	State: NV	Zip: 89146
Phone: (702) 486-4400	Title: Pharmacy tech.	Number of Employed Hours: 35,297.00	
Description of Duties:			

Business Name: Walmart Pharmacy			From - To (MM/YY – MM/YY): 11/96-2-99
Business Address: 201. N. Nellis Blvd	City: LV	State: NV	Zip: 89115
Phone: (702) 452-8118	Title: Pharmacy Tech.	Number of Employed Hours: 163,474.00	
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
8/5/15	3/1/2016	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
15CRN001730002		NLV Township / METRO		
Reason/Charge				
Conspire to violate uniform cont. subs act, 1st. / closed.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
State of NV, Ana Lemos			N/A	
Name of Business/Industry/Entity				
N/A.				

Provide explanation below:

I was in an abusive relationship with a man that was on drugs. He pistol whipped me & shot me. After leaving the hospital the police found drugs in the home. Charging me as well as him since my name was on the lease. I was placed on probation which I was let OFF 2 years early. Paid All fines and the case was closed.

Original Signature (electronic, copies or stamps not accepted)

1/9/2026
Date

I, Ana Lemos, **certify that as the designated representative for** Tera Pharmacy.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AL I am at least 21 years of age;
3. AL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ana Lemos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/19/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ana Lemos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/19/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, SaVasha Feazell-Daniels being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/23/2026

Date

Subscribed and Sworn to before me this 23rd day of January

Notary Public Signature

SAVASHA LAPONYA FEAZELL-DANIELS
NOTARY PUBLIC
STATE OF NEVADA
APPOINTMENT NO. 25121301
MY APPT. EXPIRES 10-17-2029

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Tera Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): pending change of ownership

Physical Address: 8995 W Flamingo Rd, Ste 120

City: Las Vega State: NV Zip: 89147

Mailing Address (if different from physical address): same

City: same State: same Zip: same

Telephone: 702-780-4144 Website: n/a

Licensing Company Email: stmaryrxlv@gmail.com

Section 2: Personal Information

First: Mark Middle: Magdi Last: Mahfouz

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally-Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		01/00 - 12/00	
Address	City	State	Zip
10540 Talbert Ave	Fountain Valley	CA	92708
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
California State Polytechnic University, Pomona		01/96 - 09/98	
Address	City	State	Zip
3801 W Temple Ave	Pomona	CA	91768
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of California Riverside		06/94 - 12/95	
Address	City	State	Zip
900 University Ave	Riverside	CA	92521
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Walnut High School		09/90 - 06/94	
Address	City	State	Zip
400 Pierre Rd	Walnut	CA	91789
Diploma/Degree obtained, if any			
high school diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/15 - present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
High Yield Capital			12/23 - present	
Business Address		**City**	**State**	**Zip**
3890 11th St, Ste 213		Riverside	CA	92501
Phone	**Title**			
562-533-5906	Managing Member - Head of Investor Relations			
Description of Duties				
Cultivating and nurtuting relationships with investros and bringin in new investors for opportunities in the commercial real estate space.				

Business Name			From - To (MM/YY – MM/YY)	
Hammerhead Management Services			06/20 - present	
Business Address		**City**	**State**	**Zip**
324 S Diamond Bar Blvd, #425		Diamond Bar	CA	91765
Phone	**Title**			
562-533-5906	Managing Member			
Description of Duties				
Supporting and aiding businesses with inventory sourcing solutions, as well as administrative support services including staffing and training.				

Business Name			From - To (MM/YY – MM/YY)	
Sunflower Family Investments			04/18-present	
Business Address		**City**	**State**	**Zip**
324 S Diamond Bar Blvd, #425		Diamond Bar	CA	91765
Phone	**Title**			
562-533-5906	President			
Description of Duties				
Overseeing and managing portfolio of family investments.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations, etc.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Mahfouz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/25/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, MARK MAHFOUZ, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/25/2025

Date

Subscribed and Sworn to before me this 25 day of November 2025

PLEASE SEE THE ATTACHMENT
11/25/2025

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

Signature of Document Signer No. 1

Signature of Document Signer No. 2 (if any)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 25 (Date) day of November (Month), 2025 (Year), by

(1) Mark Mahfouz

(and ~~(2)~~ _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

RAMIN MIRAGE
COMM. #2453113
Notary Public - California
Los Angeles County
My Comm. Expires July 13, 2027

Signature _____
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Personal History Application Document Date: _____

Number of Pages: _____ Signer(s) Other Than Named Above: _____

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ADDENDUM NO. 1
TO
STOCK PURCHASE AGREEMENT

IN REFERENCE to the Stock Purchase Agreement (the "Agreement") entered into between Nazokat Nigmatova, individual, (the "Seller"), and Ramy Saad Massoud and Mathew Eissa-Girges, individuals, (the "Buyers"), dated June 11, 2025 (the "Effective Date") regarding the sale of Lyfe Pharmacy, Inc. d/b/a Tera Pharmacy, the Agreement shall be revised as follows:

(1) **The following RECITALS are added for clarification:**

WHEREAS, the Corporation is the operator of a pharmacy and retail drugstore, dba Tera Pharmacy ("Store") located at 8995 W Flamingo Rd, Suite 120, Las Vegas, NV 89147 (the "Premises"); and

WHEREAS, the Buyers wish to be released from the Agreement and be replaced by Saint Mary Pharmacy, Inc., a Nevada corporation, (the "New Buyer"), and New Buyer desires to be bound by this Addendum as well as all of the terms and conditions of the Agreement—attached hereto as Exhibit A.

WHEREAS, the Corporation owns certain assets in connection with its operation of the Store, which Corporation desires to sell to New Buyer, and New Buyer desires to purchase from Corporation, all subject to and upon the terms hereinafter set forth.

(2) **The Buyers shall be released from this Agreement and replaced by Saint Mary Pharmacy, Inc., a Nevada corporation, (the "New Buyer"); and all references to "Buyer" and/or "Buyers" in the Agreement shall be amended to reflect the "New Buyer" with all representations and warranties reflecting the same.**

(3) **The Agreement will no longer reflect a stock purchase and be amended to an asset only sale where all references to "Seller" in the Agreement shall be amended to reflect the "Corporation" with all representations and warranties reflecting the same.**

(4) **Section 1.01 of the Agreement shall be deleted and amended as follows:**

1.01 *Purchase and Sale*. Subject to the terms and conditions of this Agreement, Corporation agrees to sell, transfer, assign, and convey to New Buyer, free and clear of all liens, security interests, and other encumbrances, the following items:

A. *Assets*. the furniture, trade fixtures, and the prescription files located in the Premises (collectively, the "Assets").

B. *Inventory*. All pharmaceutical merchandise at the Store (collectively, the "Inventory") listed and set forth as Schedule A.

i. A physical inventory count and valuation at the Store shall be taken on _____ (the date on which such physical inventory is actually taken is referred to herein as the

"Date of Inventory"). Prior to the commencement of the physical inventory, Corporation shall reverse and return all filled and undelivered prescriptions at the Store to stock in accordance with applicable governmental regulations, laws and requirements, providing all necessary notice to any third-party payors, reversing any adjudicated claims made in respect of such prescriptions, and shall provide New Buyer with a list of such prescriptions so that New Buyer is prepared to fill such prescriptions after the inventory. Any independent firm selected by New Buyer (the "Inventory Service") shall conduct the physical inventory, at New Buyer's expense. Corporation and New Buyer shall each arrange to have its personnel present on the Date of Inventory, who shall monitor and assist in same.

C. *Prescription Files*.

i. All prescription files, records and data utilized, maintained and/or generated by Corporation in the course of operating its licensed pharmacy in the Store (hereinafter, collectively, "Corporation's Rx Data") from the Date of Inventory (as hereinafter defined) and going back no less than the greater of (i) the period of time required by federal and state law and (ii) one (1) year (the "Required Time Period"). Corporation's Rx Data shall include all hard copy prescriptions, signature logs, patient profiles, patient refill histories, customer lists, and all electronic data of the same maintained in any format by Corporation. If Corporation has not operated in the Store for the Required Time Period prior to the Date of Inventory, the Required Time Period shall be such shorter period as Corporation has operated in the Store. In addition, to the extent Corporation's Rx Data is maintained in electronic format, New Buyers may elect (in its discretion) to convert and transfer all or any portion of such electronic Corporation's Rx Data, including for periods outside of the Required Time Period. Corporation will work in good faith with New Buyer to transfer Corporation's Rx Data to New Buyer in the most effective, efficient, and secure manner. Corporation shall fully cooperate and assist New Buyer in New Buyer's efforts to convert or transfer Corporation's Rx Data, using such means and efforts as determined by New Buyer in his sole discretion.

ii. Corporation's Rx Data shall be transferred to New Buyer exclusively, shall not be shared with any third parties, and shall not be diminished or removed from the Premises between the date of execution of this Agreement and the Date of Inventory.

D. *Goodwill*. In consideration of New Buyer's acquisition of the Inventory and Corporation's Rx Data as set forth above, and at no additional cost to New Buyer, all goodwill with respect to the Assets being sold hereunder.

E. *Exclusions*. Excluded from this sale is all cash located either at the Premises or in Corporation's bank accounts, all of Corporation's accounts receivables accrued up to and including the Closing Date, and all of Corporation's existing rights to its name "Lyfe Pharmacy, Inc." and its stock.

F. *Allocation*. Buyers and Corporation agree the allocation of Purchase Price shall be determined to include withholding all amounts necessary to pay any outstanding liens, loans, or other encumbrances on the Store as at the Closing, if any.

(5) Additional sections of the Agreement shall be deleted and amended as follows:

3.01 (a) *Title*. Corporation is the sole owner of and has good and merchantable title to all of the Assets, and all the Assets will be free and clear of security interests, liens and other encumbrances at Closing.

3.01 (e) *No Liens*. The Assets are sold free and clear of any liens, security interests, charges, or encumbrances.

3.01 (h) *Resignation/Release*. This section is no longer applicable and intentionally deleted.

4.01 (e) *Financial Condition of Corporation*. New Buyer agrees, represents, and warrants that he is fully familiar with the financial condition of the Buyers and Corporation, that he has conducted any and all due diligence desired to his satisfaction, that he was provided with all books and records of the Corporation, that he had ample opportunity to seek the advice of accountants, attorneys, and/or financial professionals, that he has conducted his own independent investigation and assessment as to the financial condition of the Buyers and Corporation, that Corporation has not had control and has not been involved in the operations or affairs of the Premises or Store, and that he is not relying on any statements, representations, promises, actions, or inactions by Seller, Corporation, or anyone else in making his decision to purchase the Assets and Inventory, as provided herein.

4.03 *Investment Purpose*. This section is no longer applicable and intentionally deleted.

5.04 *Notices*. All communications or notices required or permitted by this Agreement shall be in writing and shall be deemed to have been given at the earlier of the date when actually delivered to the other party, or when properly deposited for delivery by a nationally recognized commercial overnight delivery service, prepaid, or by deposit in the United States mail, certified or registered mail, postage prepaid, return receipt requested, and addressed as follows, unless and until either of such parties notifies the other in accordance with this Section of a change of address:

If to Buyers: _____
With Copy to: _____

If to New Buyer: _____
With Copy to: _____

If to Corporation: Nazokat Nigmatova; 10391 Lorca Major St, Las Vegas, Nevada 89141
With Copy to: Paradise Law LLC; PO Box 96537, Las Vegas, Nevada 89193
Attn: George Omar Koury, Esq.; Email: george@paradiselaw.com

(6) New Buyer shall be solely responsible for reimbursing Buyers for any and all previous monies paid to Seller after consummating the Agreement; Seller shall be solely responsible to pay Corporation any monies received from Buyers after consummating the Agreement; and New Buyer shall continue to make remaining payments directly to Corporation as per the Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Addendum as of the day and year when fully executed by all parties.

SELLER:

Nazokat Nigmatova
Signature Date: 9/19/2025

BUYERS:

Ramy Saad Massoud
Signature Date: 9/18/25

Mathew Eisa-Girges
Signature Date: 9/19/25

CORPORATION:

Lyfe Pharmacy, Inc.

By: Nazokat Nigmatova, President
Signature Date: 9/19/2025

NEW BUYER:

Saint Mary Pharmacy, Inc.

By: Mark Mahfouz, President
Signature Date: 9/19/2025

STOCK PURCHASE AGREEMENT

The Stock Purchase/Sale Agreement (this "**Agreement**"), dated as of June 11, 2025 (the "**Effective Date**"), is entered into between Nazokat Nigmatova, individual (the "**Seller**"), and Ramy Saad Massoud and Mathew Eissa-Girges, individuals (the "**Buyers**").

RECITALS

WHEREAS, Lyfe Pharmacy Inc. is a for profit corporation formed under the laws of the State of Nevada (the "**Corporation**"); and

WHEREAS, Seller owns one-hundred percent (100%) of the issued and outstanding shares of common stock in the Corporation (the "**Shares**"); and

WHEREAS, Seller wishes to sell all of her Shares in the Corporation to Buyers, and Buyers wish to purchase the Shares subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE I – *Purchase and Sale*

1.01 *Purchase and Sale*. Subject to the terms and conditions set forth herein, at the Closing, Seller hereby agrees to sell and convey to Buyers, and Buyers hereby agree to purchase from Seller the Shares of stock in the Corporation.

Stock transfer shall be made by means of a Stock Power, in form and substance satisfactory to the parties (the "**Stock Power**") and/or by means of endorsement of the stock certificate for the Stock. The Stock shall be transferred once all conditions and terms of this Agreement have been met, including but not limited to the Final Payment. At that time, the Stock Power shall be signed and delivered to the Buyers and the current stock certificate for the Stock shall be delivered by Seller to the Buyers for reissuance of the Stock in Buyers' name, with such stock certificate being newly re-issued to Buyers in exchange for the Stock Power certificate and any claims thereto.

Although the stock transfer will occur on a future date, Buyers shall immediately be added as Directors of the Corporation pursuant to the Nevada Secretary of State filing requirements.

1.02 *Purchase Price*. The total consideration to be paid for the Stock shall be one hundred fifty thousand and 00/100 dollars ($150,000.00) (the "**Purchase Price**"). The Buyers shall pay to Seller the sum of one-hundred thousand U.S. dollars ($100,000.00) (the "**Initial Payment**") at Closing, as defined in Section 2.01 of this Agreement. The remaining balance shall be paid at a rate of five thousand U.S. dollars ($5,000.00) per month, due and payable on the 1st of each month, beginning August 1, 2025 and continuing monthly for a total of ten (10) months; with the final payment being due May 1, 2026 (the "**Final Payment**").

1.03 *Method of Payment*. Buyers shall pay the Purchase Price to Seller in cash by bank transfer of immediately available funds.

EXHIBIT A

STOCK PURCHASE AGREEMENT

ARTICLE II – *Closing*

2.01 *Closing*. The closing of the transactions contemplated by this Agreement (the "**Closing**") shall take place on or before June 30, 2025 (the "**Closing Date**") by exchange of documents and signatures (or their electronic counterparts). The consummation of the transactions contemplated by this Agreement shall be deemed to occur at 12:01 a.m. Pacific Time on the Closing Date.

2.02 *Seller Closing Deliverables*. At the Closing, Seller shall deliver to Buyers the documents necessary to consummate the transaction under this Agreement.

2.03 *Buyer's Deliveries*. At the Closing, Buyers shall deliver the following to Seller:

(a) the Initial Payment pursuant to Section 1.02; and

(b) other documents necessary to consummate the transaction under this Agreement.

2.03 *Further Assurances*. The parties hereto respectively agree to reasonably cooperate with one another from and after Closing to execute and deliver such other documents as may be reasonably appropriate with respect to effecting the provisions of this Agreement and the mutual intentions of the Seller and Buyers with respect thereto.

ARTICLE III – *Representations and Warranties of Seller*

3.01 *Seller's Representations and Warranties*. Seller hereby represents and warrants to Buyer, as of the Effective Date of this Agreement and as of the Closing hereunder, as follows:

(a) *Title and Authority*. (i) Seller has clear, unencumbered record and beneficial title, free of any claim or interest of others, to the Shares; and (ii) the Shares are all of the equity interests owned by Seller in the Corporation.

(b) *Execution, Delivery and Performance of Agreement*. Seller has full power and authority to execute, deliver and perform all of the obligations of Seller under this Agreement. The execution, delivery and performance of this Agreement by Seller does not and will not: (i) conflict with or constitute a default under any agreement, indenture or other instrument, or any court or administrative order, by which the Seller, or any of the Shares owned by such Seller, is bound or affected; or (ii) violate any constitution, statute, regulation, rule, injunction, judgment, order, decree, ruling, charge, or other restriction of any government, governmental agency, or court to which Seller is subject.

(c) *Violation of Other Instruments*. Neither the execution of this Agreement nor the consummation of the transactions contemplated by this Agreement will result in the breach of any of the terms or provisions of, or constitute a default or an event which, with notice or lapse of time or both, would constitute a default under any agreement to which Seller is a party to.

(d) *Binding Agreement*. This Agreement has been duly and validly executed and delivered by Seller and is binding and valid upon Seller in accordance with its terms, except as such terms may be limited by bankruptcy, insolvency, reorganization, moratorium and other laws affecting the rights of creditors generally.

(e) *No Liens*. The Shares are sold free and clear of any liens, security interests, charges, or encumbrances.

(f) *Tax Matters*. Buyers make no representations regarding the nature or proper tax treatment of such payments. Seller agrees to and does hereby assume full responsibility to any federal, state or local taxing authorities for any tax consequences, if any, including interest and penalties, regarding income and other taxes arising out of any of the payments to her as set forth herein in the event some or all of the payments described herein are classified as taxable income to Seller by any federal, state or other taxing authority.

(g) *Non-Reliance*. Except for the representations and warranties contained in this Section 3.01, neither Seller nor any other person make any express or implied representation or warranty on behalf of or with respect to Seller, and Seller hereby disclaims any representation or warranty not contained in this Section 3.01.

(h) *Resignation/Release*. Upon stock transfer, Seller shall immediately resign from any officer, agent, employee, or other position of any kind with the Company.

3.02 *Survival of Representations and Warranties*. Each and all of the representations and warranties in this Article III shall survive the Closing hereunder.

ARTICLE IV – *Representations and Warranties of Buyer*

4.01 *Buyer's Representations and Warranties*. In addition to any and all other agreements, representations and warranties by Buyers in this Agreement, Buyers hereby represent and warrant to Seller, as of the Effective Date of this Agreement and as of Closing hereunder, as follows:

(a) *Execution, Delivery and Performance of Agreement*. Buyers have full power and authority to execute, deliver and perform all of the obligations of Buyers under this Agreement. The execution, delivery and performance of this Agreement by Buyers does not and will not (i) conflict with or constitute a default under any agreement, indenture or other instrument, or any court or administrative order, by which the Buyers are bound or affected; or (ii) violate any constitution, statute, regulation, rule, injunction, judgment, order, decree, ruling, charge, or other restriction of any government, governmental agency, or court to which Buyers are subject.

(b) *Violation of Other Instruments*. Neither the execution of this Agreement nor the consummation of the transactions contemplated by this Agreement will result in the breach of any of the terms or provisions of, or constitute a default or an event which, with notice or lapse of time or both, would constitute a default under the Articles of Incorporation or the Bylaws of the Corporation, or any lease, license, instrument or other agreement to which the Corporation is a party or by which its property is bound.

(c) *Binding Agreement*. This Agreement has been duly and validly executed and delivered by Buyers and is binding and valid upon Buyers in accordance with its terms, except as such terms may be limited by bankruptcy, insolvency, reorganization, moratorium and other laws affecting the rights of creditors generally.

(d) *Tax Matters*. Seller makes no representations regarding the nature or proper tax treatment of the transfer of the Shares. Buyers agree to and does hereby assume full responsibility to any federal, state or

local taxing authorities for any tax consequences, if any, including interest and penalties, regarding income and other taxes arising out of the transfer of Shares to him as set forth herein, whether such consequences affect Buyers of the Corporation, in the event the transfer described herein is classified as taxable income to Buyers by any federal, state or other taxing authority.

(e) *Financial Condition of Corporation*. Buyers agree, represent, and warrant that they are fully familiar with the financial condition of the Corporation, that they have conducted any and all due diligence desired to his satisfaction, that they were provided with all books and records of the Corporation, that they had ample opportunity to seek the advice of accountants, attorneys and/or financial professionals, that they have conducted their own independent investigation and assessment as to the financial condition of the Corporation, that Seller has not had control and has not been involved in the operations or affairs of the Corporation, and that they are not relying on any statements, representations, promises, actions or inactions by Seller in making their decision to purchase the Shares.

(f) *Non-Reliance*. Except for the representations and warranties contained in this Section 4.01, neither Buyers nor any other person make any express or implied representation or warranty on behalf of or with respect to Buyers, and Buyers hereby disclaim any representation or warranty not contained in this Section 4.01.

4.02 *Survival of Representations and Warranties*. Each and all of the representations and warranties in this Article IV shall survive the Closing hereunder.

4.03 *Investment Purpose*. Buyers are acquiring the Shares solely for its own account for investment purposes and not with a view to, or for offer or sale in connection with, any distribution thereof or any other security related thereto within the meaning of the Securities Act of 1933, as amended (the "Securities Act"). Buyers acknowledge that Seller has not registered the offer and sale of the Shares under the Securities Act or any state securities laws, and that the Shares may not be pledged, transferred, sold, offered for sale, hypothecated or otherwise disposed of except pursuant to the registration provisions of the Securities Act or pursuant to an applicable exemption therefrom and subject to state securities laws and regulations, as applicable. Buyers are able to bear the economic risk of holding the Shares for an indefinite period (including total loss of its investment), and has sufficient knowledge and experience in financial and business matters so as to be capable of evaluating the merits and risk of their investment.

4.04 *Brokers*. No broker, finder, or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Buyers.

4.05 *Legal Proceedings*. There are no Actions pending or, to Buyers' knowledge, threatened against or by Buyers that challenge or seek to prevent, enjoin or otherwise delay the transactions contemplated by this Agreement.

ARTICLE V – *Miscellaneous*

5.01 *Entire Agreement; Amendment; and Waivers*. This Agreement, and the agreements required to be delivered pursuant hereto constitute the entire agreement between the parties pertaining to the subject matter hereof, and supersede all prior and contemporaneous agreements, understandings, negotiations and

discussions of the parties, whether oral or written, and there are no warranties, representations or other agreements between the parties in connection with the subject matter hereof, except as specifically set forth herein. No amendment, supplement, modification, waiver, or termination of this Agreement shall be binding unless executed in writing by the party to be bound thereby. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provision of this Agreement, whether or not similar, unless otherwise expressly provided.

5.02 *Costs and Expenses*. Except as may be otherwise agreed in writing by the parties, each party shall pay its own costs and expenses of (i) consummating the sale/purchase of the Shares and (ii) other matters described in this Agreement and/or in documents executed and/or delivered in accordance with this Agreement.

5.03 *Benefit; Assignment*. This Agreement shall be binding upon and shall inure to the benefit of and shall be enforceable by Buyers and Seller and their respective successors and assigns. This Agreement (and any rights, obligation or liabilities hereunder) may not be assigned or delegated in whole or in part by either party without the prior written consent of the other party.

5.04 *Notices*. All communications or notices required or permitted by this Agreement shall be in writing and shall be deemed to have been given at the earlier of the date when actually delivered to the other party, or when properly deposited for delivery by a nationally recognized commercial overnight delivery service, prepaid, or by deposit in the United States mail, certified or registered mail, postage prepaid, return receipt requested, and addressed as follows, unless and until either of such parties notifies the other in accordance with this Section of a change of address:

If to Corporation:	8995 W Flamingo Rd, Suite 120, Las Vegas, Nevada 89147
If to Buyer:	_____
With a copy to:	_____
If to Seller:	10391 Lorca Major St, Las Vegas, Nevada 89141
With a copy to:	Paradise Law LLC; PO Box 96537, Las Vegas, Nevada 89193 Attn: George Omar Koury, Esq; Email: george@paradiselaw.com

5.05 *Attorney's Fees*. If any legal action or other proceeding is brought for the enforcement of this Agreement, or because of an alleged dispute, breach or default relating to this Agreement, the successful or prevailing party shall be entitled to recover reasonable attorneys' fees and other costs incurred in such action or proceeding, in addition to any other relief to which it or they may be entitled.

5.06 *Counterparts*. This Agreement may be executed in several counterparts, each of which shall be deemed an original, but such counterparts shall together constitute but one and the same Agreement. For the purposes hereof, facsimile signatures shall be as binding as original signatures.

5.07 *Headings*. The Article and Section headings in this Agreement are inserted for convenience of reference only and shall not constitute a part hereof.

5.08 *Severability*. If any provision, clause or part of this Agreement or the application thereof under certain circumstances is held invalid, the remainder of this Agreement, or the application of such provision, clause or part under other circumstances, shall not be affected thereby.

5.09 *Governing Law*. This Agreement shall be construed and interpreted according to the laws of the State of Nevada, without regard to the conflict of law principles thereof.

5.10 *Best Efforts*. Each of the parties shall use their respective best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, all things reasonably necessary, proper or advisable to consummate the transactions contemplated by this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above by their respective officers thereunto duly authorized.

SELLER: _____
Nazokat Nigmatova
Signature Date: 6-11-25

BUYER: _____
Ramy Saad Massoud
Signature Date: 6-11-25

BUYER: _____
Mathew Eissa-Girges
Signature Date: 6/11/25

ACCEPTED: _____
Lyfe Pharmacy, Inc.
By: Nazokat Nigmatova
Its: President & Secretary
Signature Date: 6-11-25

Saint Mary Pharmacy Inc

Tera Pharmacy

Listing of officers, directors, and stockholders

Mark Mahfouz – Pres / Treasurer / Director and 100% stockholder

Giselle Acosta – Secretary

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and **not transferable money order or cashier's check only)**

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒New OUTSOURCING FACILITY
☐Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: ORION SPECIALTY LABS LLC

Physical Address: 1710 WHITNEY MESA DRIVE

City: HENDERSON State: NV Zip Code: 89014

Telephone: 702-347-4086 Fax: 725-258-6018

Toll Free Number: 800-827-3064 (Required per NAC 639.708)

E-mail: kim@orionspeclabs.com Website: www.orionspeclabs.com

Supervising Pharmacist: Justin Curnutt Nevada License #: 18338

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral
☒ ☐ Sterile Compounding
☒ ☐ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: _____

FEI Number (From FDA application): 3040172058

Please provide the name of the facility as registered with the FDA and the registration number:
Orion Specialty Labs, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Justin Curnutt Nevada License Number: 18338

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: NV20232963763

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Kimberly Moller

Original Signature of Person Authorized to Submit Application, no copies or stamps

Kimberly Moller — Print Name of Authorized Person

2/10/2026 — Date

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: NEVADA

Parent Company if any: _____

Address: 1710 WHITNEY MESA DRIVE

City: HENDERSON State: NV Zip: 89014

Telephone: 702-347-4086 Fax: 725-258-6018

Contact Person: KIMBERLY MOLLER

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) KIMBERLY MOLLER [redacted]
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? January 5, 2024

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

ORION SPECIALTY LABS, LLC

List of Officers and Directors

Kimberly Moller:	Sole Member Sole Officer and Director

ORION SPECIALTY LABS, LLC

MEMBERSHIP INTEREST REGISTRY

Kimberly Moller	100 Membership Units

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Orion Specialty Labs, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 11/27/2023, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 09/16/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202509166088904
You may verify this certificate online at https://www.nvsilverflume.gov/home

Registered Outsourcing Facilities

Facilities Registered as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 11/14/2025

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Search: orion

Show 10 entries

Export Excel

Facility	Contact	Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]	Intends to Compound Sterile Drugs From Bulk Substances [6]
Orion Specialty Labs, LLC	Kimberly Mattera [redacted]	9/19/2025	9/19/2025	Not yet inspected	N/A	N/A	N/A	Yes

Showing 1 to 1 of 1 entries (filtered from 93 total entries)

Previous 1 Next

Feedback

Notes

1. The "Initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and the establishment fee was paid in full).

   Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. A facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

   Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect according to a risk-based schedule. FDA plans to inspect outsourcing facilities within a reasonable period of time following initial registration, once it is confirmed that the facility has initiated drug production and distribution. However, the exact timing of the inspections can be affected by a number of variables, including the number of outsourcing facility registrants, other inspection priorities, and the operational status of the newly registered outsourcing facility.

   Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and other Actions (/node/363232) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

   Inspections may take place over several days, weeks or longer. The date of the inspection is the date a Form FDA 483 listing the investigators' observations was issued. If no FDA Form 483 was issued, the date is the last day of the inspection.

3. A Form FDA 483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.
4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.
5. "Closed" means the inspection has been closed without further action. "Open" means FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letter, seizure or injunction.
6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A" indicates the registered outsourcing facility has not provided this information.
7. This outsourcing facility was the subject of at least one previous inspection relating to compounding that resulted in a Form FDA 483, warning letter or other action. For information about such inspections and resulting actions, visit Compounding: Inspections, Recalls, and other Actions (/node/363232).
8. A remote regulatory assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted remotely, to evaluate compliance with applicable FDA requirements. These assessments assist in protecting human and animal health, inform regulatory decisions and verify certain information submitted to the agency.
9. Based on inspectional findings, the inspection revealed significant issues. As a result, the outsourcing facility may have either initiated a recall on their own following conversation(s) with the FDA investigator or FDA recommended a recall at the conclusion of the inspection or both. Additionally, the outsourcing facility may have conducted multiple recalls or recalled multiple drugs.

Was this page helpful? * (required)

Yes

No

Submit

An official form of the United States government. Provided by Touchpoints

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☑ ANNUAL ☐ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

Orion Specialty Labs, LLC
NAME OF ENTITY

NV20232963763
Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☐ Corporation
☐ This corporation is publicly traded, the Central Index Key number is:

☐ Nonprofit Corporation (see nonprofit sections below)

☑ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of	Business Number
FVAguilar	E365310222023-6
	Filing Number
	202553173903
Secretary of State	Filed On
State Of Nevada	09/15/2025 14:45:48 PM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.
☐ 001 - Governmental Entity
☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C § 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. §501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required
☐ Yes - the "Charitable Solicitation Registration Statement" is required.
☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
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Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE Manager:

KIMBERLY MATTERA			USA	
Name			Country	
[redacted]	[redacted]		SC	[redacted]
Address	City		State	Zip/Postal Code

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X KIMBERLY MATTERA	Manager	09/15/2025
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*	Title	Date

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Orion Specialty Labs, LLC

Nevada Business Identification # NV20232963763
Expiration Date: 11/30/2026

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/15/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202509156085119
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site ORION SPECIALTY LABS, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1710 WHITNEY MESA DRIVE

City HENDERSON State NEVADA Zip 89014

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-347-4086 Website www.orionspeclabs.com

Licensing Company Email kim@orionspeclabs.com

Section 2: Personal Information

First KIMBERLY Middle ANN Last MOLLER

Alias(es, nicknames, name changes, etc.) KIMBERLY MATTERA - MAIDEN NAME

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
TOTENVILLE HIGH SCHOOL		09/85 - 06/89	
Address	**City**	**State**	**Zip**
100 LUTEN AVENUE	STATEN ISLAND	NY	10312
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/23 - Present	[redacted]			
01/10 - 05/23	[redacted]			

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: VESEY ENTERPRISES, INC.				From - To (MM/YY – MM/YY): 06/2013 - Present
Business Address: 168 CENTRAL AVENUE		City: FARMINGDALE	State: NY	Zip: 11735
Phone: 212-245-3413	Title: PRESIDENT			
Description of Duties: PRESIDENT AND OWNER OF HOLDING COMPANY FOR VARIOUS BUSINESS INTERESTS				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 11/6/2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KIMBERLY A. MOLLER

Print Name (First, Last)

Kimberly Moller

Original Signature (electronic, copies or stamps not accepted)

11/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of South Carolina, ss. County of Horry

I, Kimberly Moller, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Kimberly Moller

Original Signature

11/6/2025

Date

Subscribed and Sworn to before me this 6 day of November.

Notary Public Signature

David Gray
Notary Public
State of South Carolina
My commission expires 12/1/2032

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Orion Specialty Labs LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 1710 Whitney Mesa Drive

City: Henderson State: NV Zip: 89014

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-347-4086 Toll Free # (NAC 639.708, NRS 639.23286): 800-827-3064

Fax: 725-258-6018 Contact Email: kim@orionspeclabs.com

Website: www.orionspeclabs.com

Nevada Business License # (if applicable) NV20232963763

Supervising/Managing Pharmacist Name (NRS 639.220): Justin Curnutt

Supervising/Managing Pharmacist NV Pharmacist Registration #: 18338

Name of Designated Person(s) as defined by revised USP-797 guidelines: Hayes Attia, RPT

Email of Designated Person(s): hayes@orionspeclabs.com

Telephone of Designated Person(s): 702-347-4086

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? startup construction phase-est certification Q2 2026

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Weekly

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Testosterone Injectable Solutions

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL BIO PHARMA

Address: 840 RESEARCH PARKWAY SUITE 546

City: OKLAHOMA CITY State: OK Zip: 73104

Telephone: (405) 271-1144

13. What is your procedure for visual inspection of compounded sterile products?

1. Determine if the finished preparation appearance is as expected (correct final fill volume)
2. Remove any temporary labels on the container prior to performing inspection
3. Ensure preparation labels not on the preparation containers are isolated and segregated from other preparations
4. Examine preparations against a matte black background and against a non-glare white background using an incandescent light.
5. Use higher illumination intensity sufficient to detect particles for preparations where solutions are colored, opaque, or in a container other than clear glass
6. Inspect for defects such as visible particulate, leakage, cloudiness, improper seal, crystal, discoloration, or precipitation

14. How often do you perform glove fingertip and medial fill testing?

Gloved fingertip testing: initially and every six months
Media fill testing: initially and every six months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

1. Hand hygiene
2. Garbing (i.e., gloving, donning, and doffing for non-hazardous drug handling and compounding)
3. Handling, receiving, unpacking, and storing procedures
4. Proper use of primary engineering controls (PECS)
5. Principles of high-efficiency particulate air (HEPA) filtered unidirectional airflow within the ISO Class 5 environment
6. Sanitization procedures (i.e., cleaning and disinfecting)
7. Aseptic techniques which include assessment by gloved fingertip, thumb sampling, and media fill testing
8. Environmental assessments (air and surface sampling)
9. cGMP compliant

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Cleaning of PEC and equipment:
1. Cleaning agent: equipment and all interior surfaces of the PEC cleaned daily on compounding days, weekly on non-compounding days, and when surface contamination is known or suspected (sterile TB1 and Peridox RTU)
2. Disinfectant agent: equipment and all interior surfaces of the PEC cleaned daily, before and after compounding, and when surface contamination is know or suspected (sterile TB1)
3. Sporocidal agent: monthly for compounding and prior to introducing any equipment or supplies to the cleanroom (material and equipment sanitization) (sterile Peridox RTU)

Sequence of cleaning PEC: ceilings --> walls --> back of PEC --> items on the DCA --> DCA
Top to bottom, left to right

Our SOPs have detailed descriptions of the entire cleaning procedure for PEC and SEC
Floors of SEC and Anteroom: daily (cleaning agent), monthly (sporocidal)
Walls and ceiling of SEC and Anteroom: monthly (sporocidal)

17. Who performs the sterile compounding process at your facility?

Qualified & trained aseptic technicians that are media fill qualified

18. Who is responsible and accountable for the sterile compounding process at your facility?

Nahla Ahmed RPh - Pharmacist in Charge

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

3PL Supplier (FedEx/UPS) with a priority service of no longer than 2-Day Express. Shipping validation will be performed for cold-chain products, if applicable.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Class II, Type B2 Biological Safety Cabinet (Thermo Fisher 1300 Series)		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device: N/A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

As a registered 503B outsourcing facility, all products are shipped to hospital/hospital systems or doctor's offices for Office Use Only. Products are not directly shipped to patients or consumers so no information is required to be provided to them. Receiving facilities are provided with appropriate hazardous drug handling and disposal instructions in product documentation (labels, package insert, and/or facility education materials).

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

All new employees must complete didactic, observational, and hands-on training before performing any independent compounding of sterile hazardous drugs

Phase 1: Orientation and regulatory awareness
Overview of USP <797> Sterile Compounding and USP <800> Hazardous Drug Handling
OSHA Hazard Communication Standard (29 CFR 1910.1200) Understanding Safety Data Sheets
PPE categories and donning/doffing order, routes of exposure and potential health effects, emergency and spill management procedures

Phase 2: Facility and workflow training
Controlled areas: negative pressure buffer rooms, containment secondary engineering control (C-SEC)
Primary engineering controls: Biological Safety Cabinet (BSC) Traffic flow and demarcation zones between sterile and non-sterile areas, HD storage areas (negative pressure and venting), waste segregation: hazardous vs non-hazardous, cleaning and disinfection

Phase 3: Aseptic and hazardous handling skills
Hand hygiene and garbing sequence, proper donning of PPE: chemotherapy gown, double gloves, hair/beard covers, shoe covers, mask, face shield if needed
Proper syringe and vial handling, techniques to prevent HD aerosolization or spills, decontamination and deactivation process, environmental monitoring basics

Each employee must participate in a spill management demonstration using mock HD solution, exposure incident response review (eye wash, skin wash, reporting), waste disposal protocol for PPE, sharps, and containers

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Testosterone Injectable Solutions

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Garbing and gloved fingertip testing: initially and every six months
Media fill testing: initially and every six months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

Active air sampling will be performed a minimum of once per week but always on days when production is performed

5. What is the frequency for completing surface sampling? Surface sampling will be performed a minimum of once per week but always on days when production is performed	
6. What is the frequency for using sporicidal agents? Cleaning with sporicidal agents (Peridox) is performed once per month at a minimum.	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes ☐ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes ☐ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Curnutt

Name of Person who Completed the Form

Pharmacist-in-Charge

Title

Signature (copies or stamps not accepted)

2/5/2026

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: CAD-Ray Distribution, INC

Physical Address: 8400 W Sunset Rd Suite 300

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): [redacted]

City: Fallston State: MD Zip: [redacted]

Telephone: 833-223-7292 Website: www.cad-ray.com

Name of Designated Representative (DR): Armen Vartanian

Licensing Company Email: compliance.cadray@lighthouseai.com DR Email: Armen@oceanviewcap.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Dentists		■ Others: Virtual

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: CAD-Ray Distribution, Inc.

Mailing Address: [redacted]

City: Fallston State: MA Zip: [redacted]

Telephone: 833-223-7292 Email: compliance.cadray@lighthouseai.com

Contact Person Name: Jonathan Acker

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medit USA, Inc.
Address: 4490 Von Karman Ave, Suite 150 City: Newport Beach State: CA Zip: 92660

Name: 3Shape, Inc.
Address: 430 Mountain Avenue, Suite 113 City: New Providence State: NJ Zip: 07974

Name: SprintRay, Inc.
Address: 2710 Media Center Drive, Suite 100A City: Los Angeles State: CA Zip: 90065

Name: DOF USA
Address: 23 Mauchly, Suite 107 City: Irvine State: CA Zip: 92618

Section 4: Publicly Traded Corporation

State of Incorporation: NA
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NV
Parent Company (if any): NA owned by shareholders
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: NA
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: See ownership chart
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

CAD-Ray Distribution, Inc.

Facility Name

Armen Vartanian

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12-2-25

Date

Board Use Only	Date Received: 12/11/25	Amount: $1000 CK 2231

FDA

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
CAD-RAY DISTRIBUTION, INC
8400 W Sunset Rd
Suite 300
Las Vegas, NV 89113
Registration Number: 3020762698
FEI Number*: 3020762698
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2026

Owner/Operator:
CAD-Ray Distribution, INC[6]
8400 W Sunset Rd
Suite 300
Las Vegas, NV US 89113
Owner/Operator Number: 10083116[7]

Official Correspondent:
Jonathan B Acker
8400 W Sunset Rd
Suite 300
Las Vegas, NV 89113
Phone: 1-202-8416615

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10083116&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryN
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10083116&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryN

Page Last Updated: 12/15/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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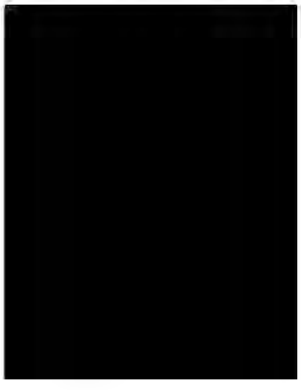
CAD-Ray Distribution, Inc.

Ownership Info

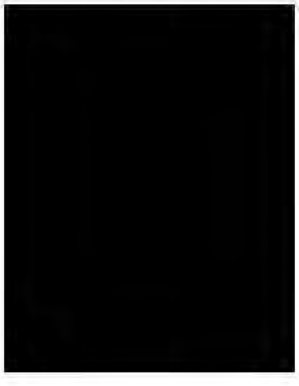
Armen Mirzayan, President/CEO



Richard LaFergola, VP/COO



Jonathan Acker, Co-Owner



Diron Ohanian, Co-Owner



Armen Vartanian, Co-Owner



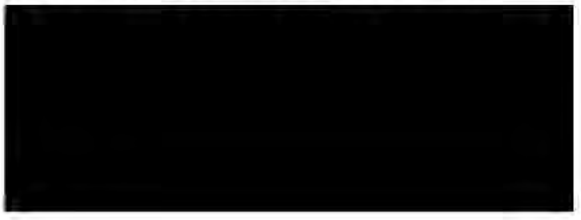
Raffy Mirzayan, Director/Co-Owner



John Adomian, Co-Owner



Zareh Kouyoumdjian, Co-Owner



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **CAD-Ray Distribution Inc.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/16/2021, and in good standing in this State.

I further certify that the above DOMESTIC CORPORATION (78) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/19/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202511196288123
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

CAD-Ray Distribution Inc.

Organizational Documents on File	Filing Date
Articles of Incorporation-For-Profit	03/16/2021

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence CAD-Ray Distribution Inc., as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 03/16/2021, and is in good standing in this state.

STATE OF NEVADA

FRANCISCO V. AGUILAR
Secretary of State



C. MURPHY HEBERT
Chief Deputy Secretary of State

DEANNA L. REYNOLDS
Deputy Secretary for Commercial Recordings

OFFICE OF THE
SECRETARY OF STATE

Jonathan acker
8400 W sunset Rd, 3rd Flr Ste 300 ste 300
Las Vegas, NV 89113, USA

Work Order #: W2025111900937
November 19, 2025
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 958347

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Certificates	Fees	20255320546	11/19/2025 10:54:44 AM	Approved	1	$150.00	$150.00
Total							$150.00

Payments

Type	Description	Payment Status	Amount
Credit Card	[redacted]	Success	$150.00
Credit Card	Service Fee	Success	$3.75
Total			$153.75

Credit Balance: $0.00

Jonathan acker
8400 W sunset Rd, 3rd Flr Ste 300 ste 300
Las Vegas, NV 89113, USA

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **CAD-Ray Distribution Inc.** as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/16/2021, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 11/19/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202511196288122
You may verify this certificate online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 11/19/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202511196288124
You may verify this certificate online at
https://www.nvsilverflume.gov/home

Entity Information

Entity Information

Entity Name:

CAD-RAY DISTRIBUTION INC.

Entity Number:

E13114572021-7

Entity Type:

Domestic Corporation (78)

Entity Status:

Active

Formation Date:

03/16/2021

NV Business ID:

NV20212043763

Termination Date:

Annual Report Due Date:

3/31/2026

Compliance Hold:

Registered AGENT INFORMATION

Name of Individual or Legal Entity:

Armen Mirzayan

Status:

Active

CRA Agent Entity Type:

Registered Agent Type:

Non-Commercial Registered Agent

NV Business ID:

Office or Position:

Jurisdiction:

Street Address:

12656 SOUTHERN HIGHL PKY # 2059 , Las Vegas, NV, 89141, USA

Mailing Address:

OFFICER INFORMATION

☐ **View Historical Data**

Title	Name	Address	Last Updated	Status
President	Armen Mirzayan	8400 West Sunset Road, #300, Las Vegas, NV, 89113, USA	01/30/2023	Active
Secretary	Armen Mirzayan	8400 West Sunset Road, #300, Las Vegas, NV, 89113, USA	01/30/2023	Active
Director	Armen Mirzayan	8400 West Sunset Road, #300, Las Vegas, NV, 89113, USA	01/30/2023	Active
Director	Raffy Mirzayan	[redacted]	01/30/2023	Active
Treasurer	Richard Lafergola		03/16/2021	Active

< Previous ... 1 2 ... Next > Page 1 of 2, records 1 to 5 of 7 Go to Page

CURRENT SHARES

Class/Series	Type	Share Number	Value
	Authorized	15,000,000	0.001

Page 1 of 1, records 1 to 1 of 1

Number of No Par Value Shares:

0

Total Authorized Capital:

15,000

Filing History Name History Mergers/Conversions

Return to Search Return to Results

CAD-Ray Distribution, Inc.

Officer List

Armen Mirzayan, President/CEO



Richard LaFergola, VP/COO/Treasurer



Raffy Mirzayan, Director/Co-Owner



CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/18/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Nistar Risk Management 167 Blackhorse Lane North Brunswick NJ 08902	CONTACT NAME: Hope Edwards PHONE (A/C, No, Ext): (732) 538-8801 FAX (A/C, No): E-MAIL ADDRESS: hopee@nistarrisk.com
INSURED CAD-Ray Distribution, Inc. 8400 West Sunset Road Suite 300 Las Vegas NV 89113	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Hartford Underwriters Insurance Company INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** CL2451000541 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:	Y		16 SBA AP7FR9	01/19/2025	01/19/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded $
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ $ $ $ $
A	[X] UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $ 10,000	Y		16 SBA AP7FR9	01/19/2025	01/19/2026	EACH OCCURRENCE AGGREGATE [ ]	$ 1,000,000 $ 1,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N [ ] If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Certificate holder is added as Additional Insured including: Florida Dental Associationm FDC Exhibits, Gaylord Palms Resort and Convention Center and the Freeman Companies as required by written contract subject to policy terms and conditions during the Florida Dental Convention June 28-July 2, 2024.

CERTIFICATE HOLDER

Florida Dental Association
545 John Knox Rd., Ste 200
Tallahassee FL 32303

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 514042N

Application/License No. _____

CAD-RAY DISTRIBUTION INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 8400 W Sunset Rd, 3rd Flr Ste 300, Las Vegas NV 89113 (Address of Applicant/Principal), as PRINCIPAL, and Westfield Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1 Park Circle, Westfield Center OH, 44251-50001 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 11/25/25 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of December, 20 25.

APPLICANT/PRINCIPAL

jon acker
Authorized Representative

SURETY COMPANY

Surety Company's Representative

Joshua Kayser, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A RETALIATORY
Nevada Resident Agent

WESTFIELD INSURANCE COMPANY SEAL

POWER NO. 2400012 01
General Power of Attorney

CERTIFIED COPY

Westfield Insurance Co.
Westfield National Insurance Co.
Ohio Farmers Insurance Co.
Westfield Center, Ohio

Know All Men by These Presents, That WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, corporations, hereinafter referred to individually as a "Company" and collectively as "Companies," duly organized and existing under the laws of the State of Ohio, and having their principal offices in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint **MATTHEW BOCKLAGE, JAMIE BRIGGS, BRAD BULLERDIECK, SEDA GULER, BRIAN D. RUSSELL, JR., BERNARDO C. SCORZA GASPAR, ROBERT J. WOLF, BLAKE OLIVER, MARK KARR, JOSHUA KAYSER, ZACK LENZ, JOINTLY OR SEVERALLY,** of **COLUMBIA** and State of **MO** their true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in their names, place and stead, to execute, acknowledge and deliver **any and all bonds, recognizances, undertakings, or other instruments or contracts of suretyship in any penal limit** -

LIMITATION: THIS POWER OF ATTORNEY CANNOT BE USED TO EXECUTE NOTE GUARANTEE, MORTGAGE DEFICIENCY, MORTGAGE GUARANTEE, OR BANK DEPOSITORY BONDS.

and to bind any of the Companies thereby as fully and to the same extent as if such bonds were signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of each of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY and OHIO FARMERS INSURANCE COMPANY.

BE IT RESOLVED, that the President, any Senior Executive, any Secretary or any Fidelity & Surety Operations Executive or other Executive shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings and any and all notices and documents cancelling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be as binding upon The Company as if signed by the President and sealed and attested by the Corporate Secretary."

"**BE IT FURTHER RESOLVED**, that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." (Each adopted at a meeting held on February 8, 2000.)

In Witness Whereof, WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY have caused these presents to be signed by their **National Surety Leader** and **Senior Executive** and their corporate seals to be hereto affixed this **27th** day of **July**, A.D., **2022**.

Corporate Seals Affixed

WESTFIELD INSURANCE COMPANY
WESTFIELD NATIONAL INSURANCE COMPANY
OHIO FARMERS INSURANCE COMPANY

By **Gary W. Stumper.**
National Surety Leader and *Senior Executive*

State of Ohio
County of Medina ss.

On this **27th** day of **July**, A.D., **2022**, before me personally came **Gary W. Stumper**, to me known, who, being by me duly sworn, did depose and say, that he resides in **Medina, Ohio**, that he is **National Surety Leader** and **Senior Executive** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, the companies described in and which executed the above instrument; that he knows the seals of said Companies; that the seals affixed to said instrument are such corporate seals; that they were so affixed by order of the Board of Directors of said Companies; and that he signed his name thereto by like order.

Notarial Seal Affixed

By

David A. Kotnik, Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss.

CERTIFICATE

I, **Frank Carrino**, Secretary of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Companies, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Westfield Center, Ohio, this 1st day of, December A.D., 2025

By

Frank Carrino, *Secretary*

BPOAC (03-22)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG CAD-Ray Distribution, INC MDEG License # (if applicable) _____

Physical Address 8400 W Sunset Rd Suite 300

City Las Vegas State NV Zip 89113

Mailing Address (if different from physical address) 2513 Burgundy Dr

City Fallston State MD Zip 21047

Telephone 833-223-7292 Website www.cad-ray.com

Licensing Company Email compliance.cadray@lighthouseai.com

Section 2: Personal Information

First Armen Middle _____ Last Vartanian

Alias(es, nicknames, name changes, etc.) NA

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Wharton School, University of Pennsylvania		May 2014	
Address	**City**	**State**	**Zip**
3451 Walnut Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
UC Berkeley, Haas School of Business		Dec 2004	
Address	**City**	**State**	**Zip**
110 Sproul Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
BS Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/23-Present	[redacted]	Las Vegas	NV	[redacted]
10/20-10/23		Las Vegas	NV	
11/16-10/20		Glendale	CA	
1/15-11/16		Encino	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
CAD-Ray Distribution, INC			May 2017-present	
Business Address		City	State	Zip
8400 W. Sunset Rd, Ste. 300		Las Vegas	NV	89113
Phone	Title		Number of Employed Hours	
833-223-7292	Co-Owner		17,000	
Description of Duties				
• Built a national distribution company specializing in digital imaging, CAD/CAM, guided implantology, and CT technologies. • Led product expansion, partnerships, and customer adoption across dental practices.				

Business Name			From - To (MM/YY – MM/YY)	
Vital Medical Services, LLC			Jun 2015 – Present	
Business Address		City	State	Zip
701 North Brand Blvd Suite 850		Glendale	CA	91203
Phone	Title		Number of Employed Hours	
(818) 905-1700	President		20,000	
Description of Duties				
• Oversee 24/7 medical operations for government agencies including cities, schools, and police departments. • Manage compliance, staffing, and mission-critical clinical performance				

Business Name			From - To (MM/YY – MM/YY)	
Oceanview Capital Advisors, Inc.			11/1/2020 – Present	
Business Address		City	State	Zip
4471 Dean Martin Dr #907		Las Vegas	NV	89103
Phone	Title		Number of Employed Hours	
818-330-4810	President		10,000	
Description of Duties				
• Business advisory services primarily for Nevada-based companies				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section B: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

I, Armen Vartanian, **certify that as the MDEG Administrator for**

CAD-Ray Distribution, Inc.,

that I (initial that you have read and meet the following requirements):

1. AV Have a high school diploma or its equivalent;
2. AV Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AV Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AV Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Armen Vartanian
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

Board Use Only	Date Received: 12/11/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: CAD-Ray Distribution, INC

Pharmacy/Wholesaler License # (if applicable): NA

Physical Address: 8400 W Sunset Rd Suite 300

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): [redacted]

City: Fallston State: MD Zip: [redacted]

Telephone: 833-223-7292 Website: www.cad-ray.com

Licensing Company Email: compliance.cadray@lighthouseal.com

Section 2: Personal Information

First: Armen Middle: Last: Vartanian

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Wharton School, University of Pennsylvania		May 2014	
Address	**City**	**State**	**Zip**
3451 Walnut Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
UC Berkeley, Haas School of Business		Dec 2004	
Address	**City**	**State**	**Zip**
110 Sproul Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
BS Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/23-Present	[redacted]	Las Vegas	NV	[redacted]
10/20-10/23		Las Vegas	NV	
11/16-10/20		Glendale	CA	
1/15-11/16		Encino	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
CAD-Ray Distribution, INC			May 2017-present	
Business Address		City	State	Zip
8400 W. Sunset Rd, Ste. 300		Las Vegas	NV	89113
Phone	Title		Number of Employed Hours	
833-223-7292	Co-Owner		17,000	
Description of Duties				
• Built a national distribution company specializing in digital imaging, CAD/CAM, guided implantology, and CT technologies. • Led product expansion, partnerships, and customer adoption across dental practices.				

Business Name			From - To (MM/YY – MM/YY)	
Vital Medical Services, LLC			Jun 2015 – Present	
Business Address		City	State	Zip
701 North Brand Blvd Suite 850		Glendale	CA	91203
Phone	Title		Number of Employed Hours	
(818) 905-1700	President		20,000	
Description of Duties				
• Oversee 24/7 medical operations for government agencies including cities, schools, and police departments. • Manage compliance, staffing, and mission-critical clinical performance				

Business Name			From - To (MM/YY – MM/YY)	
Oceanview Capital Advisors, Inc.			11/1/2020 – Present	
Business Address		City	State	Zip
4471 Dean Martin Dr #907		Las Vegas	NV	89103
Phone	Title		Number of Employed Hours	
818-330-4810	President		10,000	
Description of Duties				
• Business advisory services primarily for Nevada-based companies				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

I, Armen Vartanian, **certify that as the designated representative for**

CAD-Ray Distribution, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AV I am at least 21 years of age;
3. AV I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AV I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AV I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AV I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AV I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Armen Vartanian

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-2-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Armen Vartanian

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/02/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Bay County

I, Armen Vartanian, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Armen Vartanian

Original Signature

12/02/2025

Date

Subscribed and Sworn to before me this 2nd day of December 2025.

Seth Riggs

Notary Public Signature

The above-name person produced DRIVER LICENSE identification

SETH RIGGS
Notary Public - State of Florida
Commission # HH639513
Expires on February 11, 2029

(Seal)

Notarized remotely online using communication technology via Proof.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CAD-Ray Distribution, INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) NA

Physical Address 8400 W Sunset Rd Suite 300

City Las Vegas State NV Zip 89113

Mailing Address (if different from physical address [redacted]

City Fallston State MD Zip [redacted]

Telephone 833-223-7292 Website www.cad-ray.com

Licensing Company Email compliance.cadray@lighthouseai.com

Section 2: Personal Information

First Armen Middle _____ Last Vartanian

Alias(es, nicknames, name changes, etc.) NA

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Wharton School, University of Pennsylvania		May 2014	
Address	**City**	**State**	**Zip**
3451 Walnut Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
UC Berkeley, Haas School of Business		Dec 2004	
Address	**City**	**State**	**Zip**
110 Sproul Hall	Berkeley	CA	94720
Diploma/Degree obtained, if any			
BS Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/23-Present	[redacted]	Las Vegas	NV	[redacted]
10/20-10/23		Las Vegas	NV	
11/16-10/20		Glendale	CA	
1/15-11/16		Encino	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CAD-Ray Distribution, INC			May 2017-present
Business Address	**City**	**State**	**Zip**
8400 W. Sunset Rd, Ste. 300	Las Vegas	NV	89113
Phone	**Title**		
833-223-7292	Co-Owner		

Description of Duties

• Built a national distribution company specializing in digital imaging, CAD/CAM, guided implantology, and CT technologies. • Led product expansion, partnerships, and customer adoption across dental practices.

Business Name			From - To (MM/YY – MM/YY)
Vital Medical Services, LLC			Jun 2015 – Present
Business Address	**City**	**State**	**Zip**
701 North Brand Blvd Suite 850	Glendale	CA	91203
Phone	**Title**		
(818) 905-1700	President		

Description of Duties

• Oversee 24/7 medical operations for government agencies including cities, schools, and police departments. • Manage compliance, staffing, and mission-critical clinical performance

Business Name			From - To (MM/YY – MM/YY)
Oceanview Capital Advisors, Inc.			11/1/2020 – Present
Business Address	**City**	**State**	**Zip**
4471 Dean Martin Dr #907	Las Vegas	NV	89103
Phone	**Title**		
818-330-4810	President		

Description of Duties

• Business advisory services primarily for Nevada-based companies

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12-2-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Armen Vartanian

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/02/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Bay County

I, Armen Vartanian, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Armen Vartanian

Original Signature

12/02/2025

Date

Subscribed and Sworn to before me this 2nd day of December 2025

Seth Riggs

Notary Public Signature

SETH RIGGS
Notary Public - State of Florida
Commission # HH639513
Expires on February 11, 2029

The above-name person produced DRIVER LICENSE as identification

Notarized remotely online using communication technology via Proof.

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: CAD-Ray Distribution, INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NA

Physical Address: 8400 W Sunset Rd Suite 300

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): [redacted]

City: Fallston State: MD Zip: [redacted]

Telephone: 833-223-7292 Website: www.cad-ray.com

Licensing Company Email: compliance.cadray@lighthouseai.com

Section 2: Personal Information

First: Armen Middle: Last: Mirzayan

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephon[redacted] Email: armen@cad-ray.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Queens Medical Center		1998-1999	
Address	**City**	**State**	**Zip**
1301 Punchbowl St	Honolulu	HI	96813
Diploma/Degree obtained, if any			
General practice residency certificate			

School Name		From - To (MM/YY – MM/YY)	
Northwestern University Dental school		1994-1998	
Address	**City**	**State**	**Zip**
school closed in 2001	Chicago	IL	
Diploma/Degree obtained, if any			
Doctorate of Dental Surgery Degree			

School Name		From - To (MM/YY – MM/YY)	
UCLA		1987-1992	
Address	**City**	**State**	**Zip**
405 Hilgard Avenue	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
BS in Physiological Sciences			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/24 - current	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
12/22-12/24		Las Vegas	NV	
From - To (MM/YY – MM/YY)		City	State	
12/21-12/22		Las Vegas	NV	
From - To (MM/YY – MM/YY)		City	State	
12/20-12/21		Las Vegas	NV	
From - To (MM/YY – MM/YY)		City	State	
7/04-8/23		Glendale	CA	
From - To (MM/YY – MM/YY)	[illegible]	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
CAD-Ray Distribution, INC			03/21-now	
Business Address		**City**	**State**	**Zip**
8400 W. Sunset Rd, Ste. 300		Las Vegas	NV	89113
Phone	**Title**			
833-223-7292	President/CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Armen mirzayan DDS Inc, DBA esthetic dentistry dental group			12/00-8/23	
Business Address		**City**	**State**	**Zip**
1080 wilshire blvd		Los Angeles	CA	90017
Phone	**Title**			
213-553-4535	President/CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

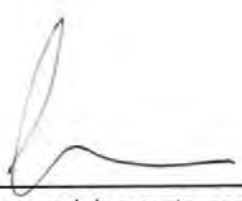
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

12/4/2025

Date

Personal History Application (Applicant's Initials AM) 6 of 7

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Armen Mirzayan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/4/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Armen Mirzayan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/4/25

Date

Subscribed and Sworn to before me this 4th day of December.

Notary Public Signature

NOTARY PUBLIC
STATE OF NEVADA
of Clark County
25-9397-01 BERNELL BRADSHAW
My Appointment Expires June 16, 2029
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: CAD-Ray Distribution, INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NA

Physical Address: 8400 W Sunset Rd Suite 300

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): [redacted]

City: Fallston State: MD Zip: [redacted]

Telephone: 833-223-7292 Website: www.cad-ray.com

Licensing Company Email: compliance.cadray@lighthouseai.com

Section 2: Personal Information

First: Jonathan Middle: Brett Last: Acker

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Fallston State: MD Zip: [redacted]

Telephone: [redacted] Email: jon@cad-ray.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Purdue University			2003 – 2007
Address	**City**	**State**	**Zip**
401 S Grant St	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
Bachelor of Science, Environmental / Environmental Health Engineering			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2015-present	[redacted]	Fallston	MD	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
CAD-Ray Distribution Inc.		Nov 2018 – Present	
Business Address	**City**	**State**	**Zip**
8400 W. Sunset Rd, Ste. 300	Las Vegas	NV	89113
Phone	**Title**		
833-223-7292	Co-Owner		

Description of Duties

Oversee national operations, vendor relations, and strategic growth across CAD-Ray's distribution network. Direct cross-functional teams spanning sales, logistics, clinical training, and customer support.

Business Name		From - To (MM/YY – MM/YY)	
Henry Schein, Inc.		May 2017 – Nov 2018	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
	Digital Technology Specialist		

Description of Duties

Managed sales, support, and clinical integration of digital technologies including CAD/CAM systems, intraoral scanners, cone-beam CTs, and digital sensors.

Business Name		From - To (MM/YY – MM/YY)	
Patterson Dental		May 2008 – May 2017	
Business Address	**City**	**State**	**Zip**
	Washington	DC	
Phone	**Title**		
	CAD/CAM Specialist		

Description of Duties

Led regional sales and training initiatives for the CEREC digital impression and CAD/CAM systems. Acted as primary liaison between dental professionals, manufacturers, and internal support divisions.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/1/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Acker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 12/2/2025

Please have this section completed in the presence of a Notary Public.

State of Maryland, ss. County of Harford

I, Jonathan Acker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 12/2/2025

Subscribed and Sworn to before me this 2 day of Dec 2 2025

Notary Public Signature

HOWARD GEOFFREY BOWERS
Notary Public - State of Maryland
Harford County
My Commission Expires Sep 22, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: CAD-Ray Distribution, INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NA

Physical Address: 8400 W Sunset Rd Suite 300

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): [redacted]

City: Fallston State: MD Zip: [redacted]

Telephone: 833-223-7292 Website: www.cad-ray.com

Licensing Company Email: compliance.cadray@lighthouseai.com

Section 2: Personal Information

First: Richard Middle: V Last: LaFergola

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Rumson State: NJ Zip: [redacted]

Telephone: [redacted] Email: rich@cad-ray.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Penn State University		2003-2007	
Address	**City**	**State**	**Zip**
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
Bachelor of Science in Finance			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020-2025	[redacted]	Rumson	NJ	[redacted]
2018-2020		Weehawken	NJ	
2013-2018		Baltimore	MD	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CAD-Ray Distribution Inc.			Aug 2018 – Present
Business Address	**City**	**State**	**Zip**
8400 W. Sunset Rd, Ste. 300	Las Vegas	NV	89113
Phone	**Title**		
833-223-7292	Co-Owner		

Description of Duties

Lead overall sales strategy, operations, and growth initiatives for CAD-Ray North America. Direct product development, market expansion, and strategic planning efforts.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/3/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard LaFergola

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 12/4/25

Please have this section completed in the presence of a Notary Public.

State of , ss. County of

I, Richard LaFergola , being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 12/4/25

Subscribed and Sworn to before me this 4th day of December, 2025

Notary Public Signature

WESLEY MARCHAK
Notary Public, State of New Jersey
My Commission Expires 04/08/2027

(Seal)

CAD-Ray Distributions, Inc. Employee List

Name	Last Name	Title	Cell Phone	Work Email	Street Address 1	Unit	City	State	Postal Code	Date of Birth
Acker, Jonathan	Acker	COO	[redacted]							
Allen, Griffen	Allen	CAD/CAM Technician								
Bonner, Damien	Bonner	VP Bus Dev								
DeLuca, Frank	DeLuca	Sales and Service								
Garcia, Ericka	Garcia	Technical/Clinical Support Specialist								
Gramley, Heather	Gramley	Technical and Clinical Support								
Hartrick, Laura	Hartrick	VP Sales								
LaFergola, Rich	LaFergola	President								
Larson, Kaila	Larson	Clinical/Technical Support Specialist								
Lathero, Destaney	Lathero	Technical/Clinical Support Specialist								
Mattern, Ryan	Mattern	Technical and Clinical Support								
Minatrea, Jason	Minatrea	CAD/CAM Specialist								
Mirzayan, Armen	Mirzayan	CEO								
Newman, Matt	Newman	OPS/Marketing								
Vartanian, Armen	Vartanian	CFO								

10B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☒ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ■ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03038	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: FOOT CARE STORE, LLC D/B/A DIA-FOOT

Physical Address: 4280 WEST WINDMILL LANE STE 111

City: LAS VEGAS, State: NV Zip: 89139

Mailing Address (if different from physical address): 3281 FAIRLANE FARMS ROAD, STE 7

City: WELLINGTON State: FL Zip: 33414

Telephone: 561-791-1213 Website: WWW.DIA-FOOT.COM

Name of Designated Representative (DR): SARA MICHELLE SIMONSON

Licensing Company Email: JAY@DIA-FOOT.COM DR Email: MICHELLE @DIA-FOOT.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: DIABETIC FOOTWEAR

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/16/26
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FLORIDA

Parent Company (if any): PACIFIC FOOTWEAR COMPANY,INC D/B/A PRIORTY FOOTWEAR

Corporation/Organization Name: FOOT CARE STORE,LLC D/B/A DIA-FOOT

Mailing Address: 3281 FAIRLANE FARMS ROAD, STE 7

City: WELLINGTON State: FL Zip: 33414

Telephone: 561-791-1213 Email: JAY@DIA-FOOT.COM

Contact Person Name: JAY JOSEPHSON

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

FOOT CARE STORE, LLC

Facility Name

JAY A JOSEPHSON

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/16/26

Date

Board Use Only	Date Received: 1/21/26	Amount: No payment

Maria Herrera

From: jay@dia-foot.com
Sent: Wednesday, February 4, 2026 12:21 PM
To: Maria Herrera
Subject: RE: [EXTERNAL] RE: FW: RE: [External Message] Nevada Wholesaler Application-Foot Care Store, Inc. (WH03038) CHOW
Attachments: Foot care stor,llc cert.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Maria,
Response you requested.
1. Have attached the Nevada State Business License.
2. Foot Care Store ,LLC does not have any officers/directors. Robert Gaynor is the Manager.

Regards,

Jay A. Josephson
Chief Financial Officer
Dia-Foot
3281 Fairlane Farms Rd., Ste 7
Wellington, FL 33414
Jay@dia-foot.com
561-791-1213

From: "Maria Herrera" <m.herrera@pharmacy.nv.gov>
Sent: 2/4/26 2:55 PM
To: "jay@dia-foot.com" <jay@dia-foot.com>,"michelle@dia-foot.com" <michelle@dia-foot.com>
Subject: [EXTERNAL] RE: FW: RE: [External Message] Nevada Wholesaler Application-Foot Care Store, Inc. (WH03038) CHOW

CAUTION: This email originated from outside of this organization. Do not click on links or open attachments unless you recognize the sender and know the content is safe.

From: jay@dia-foot.com <jay@dia-foot.com>
Sent: Tuesday, February 3, 2026 2:55 PM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: RE: [EXTERNAL] RE: [External Message] Nevada Wholesaler Application-Foot Care Store, Inc. (WH03038) CHOW

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Maria,

We are a wholesale distributer of devices of product from within

our own company.

Regards,

NAC 639.573(6)(e) ✓

Jay A. Josephson

Chief Financial Officer

Dia-Foot

3281 Fairlane Farms Rd., Ste 7

Wellington, FL 33414

Jay@dia-foot.com

561-791-1213

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
FOOTCARE STORE LLC
Business Trade Name:
DIA-FOOT

3281 Fairlane Farms Rd Ste 7
Wellington, FL 33414
Registration Number: 3005472804
FEI Number*: 3005472804
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2026

Owner/Operator:

Anodyne[6]
5050 S 2nd St
Milwaukee, WI US 53207
Owner/Operator Number: 10049577[7]

Official Correspondent:
Bobby Kanter
5050 S 2nd St
Milwaukee, WI 53207
Phone: 1-414-8771950

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 01/12/2026

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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State of Florida
Department of State

I certify from the records of this office that FOOT CARE STORE, LLC is a limited liability company organized under the laws of the State of Florida, filed on December 16, 2025, effective January 16, 1996.

The document number of this limited liability company is L25000552011.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Eighth day of January, 2026

Secretary of State

Tracking Number: 3769208353CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

FOOT CARE STORE, LIMITED LIABILITY COMPANY

Nevada Business Identification # NV20263512760
Expiration Date: 01/31/2027

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/20/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202601206426882
You may verify this certificate online at https://www.nvsilverflume.gov/home

THE HARTFORD

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy STE 206
Reno, NV 89521

RIDER

Attached to and forming part of Bond # 21BSBIP9376 ,
on behalf of Foot Care Store, Inc.
of 4280 West Windmill Lane, Ste 111, Las Vegas, NV 89139
in favor of Nevada State Board of Pharmacy
and in the amount of One Hundred Thousand ($100,000.00) Dollars.

It is understood and agreed that effective February 26, 2026
The Principals name shall be changed
from Foot Care Store, Inc.
to Foot Care Store LLC

All other conditions and terms remain as originally written.

Signed, Sealed, and Dated January, 14th , 2026

Hartford Fire Insurance Company

By: _____
Joelle L LaPierre , Attorney-in-Fact

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 21BSBIP9376

Application/License No. WH03038

FOOT CARE STORE, LLC, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
4280 West Windmill Lane Ste 111, Las Vegas, NV 89139, as
Address of Applicant/Principal
PRINCIPAL, and Hartford Fire Insurance Co, a
Surety Company
corporation organized under the laws of the state of CT
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
4280 West Wind Mill Lane, Ste 111, Las Vegas, NV 89139 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 26, 2026.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of January, 2026.

APPLICANT/PRINCIPAL

COMPANY

_____
Authorized Representative

SURETY

_____
Surety Company's Representative

_____, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

Countersigned by:

_____
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: THE BALDWIN GROUP SOUTHEAST LLC
Agency Code: 21-220187

- ☒ **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- ☐ **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- ☐ **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Joelle L LaPierre
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 21BSBIP9376
Naming Foot Care Store LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of January 14, 2026.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 1/14/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
The Baldwin Group Southeast LLC
4211 W Boy Scout Blvd Ste 800
Tampa FL 33607

License#: L002281

CONTACT NAME:
PHONE (A/C, No, Ext): 813-984-3200 **FAX (A/C, No):** 813-984-3201
E-MAIL ADDRESS: Certificates@baldwin.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Hanover Insurance Company	22292
INSURER B : Hanover American Insurance Co	36064
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
ANODLLC-01
Foot Care Store, LLC DBA Dia-Foot
Foot Care Store, Inc.
3281 Fairlane Farms Road
Wellington FL 33414

COVERAGES **CERTIFICATE NUMBER:** 1064393639 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			ZHJ-M000401-00	3/27/2025	3/27/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			AWJ J900007	4/13/2025	4/13/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			UHJ 9938089 03	4/13/2025	4/13/2026	EACH OCCURRENCE	$ 3,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 3,000,000
	DED X RETENTION $ 0						Products Excluded	$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED?	N/A					E.L. EACH ACCIDENT	$
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products Liability			LHJ 9938103 03	4/13/2025	4/13/2026	Claim Limit Claim Deductible	5,000,000 50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: 4280 West Windmill Lane, Ste 111 Las Vegas NV 89139

CERTIFICATE HOLDER

Nevada State Pharmacy Board
985 Damonte Ranch Parkway
Suite 206
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG FOOT CARE STORE LLC, dba DIA-FOOT MDEG License # (if applicable) MP03088

Physical Address 4280 WEST WINDMILL LANE, SUITE 111

City LAS VEGAS State NV Zip 89139

Mailing Address (if different from physical address) 3281 FAIRLANE FARMS RD

City WELLINGTON State FL Zip 33414

Telephone 702-970-7166 Website WWW.DIA-FOOT.COM

Licensing Company Email JAY@DIA-FOOT.COM

Section 2: Personal Information

First SARA Middle MICHELLE Last SIMONSON

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City BLUE DIAMOND State NV Zip [redacted]

Telephone [redacted] Email MICHELLE@DIA-FOOT.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
PEACE COLLEGE		08/02-05/06	
Address	City	State	Zip
15 EAST PEACE ST	RALEIGH	NC	27604
Diploma/Degree obtained, if any			
BACHELORS - BIOLOGY			

School Name		From - To (MM/YY – MM/YY)	
PEACE COLLEGE		08/02-08/04	
Address	City	State	Zip
15 EAST PEACE ST	RALEIGH	NC	27604
Diploma/Degree obtained, if any			
ASSOCIATES OF ARTS			

School Name		From - To (MM/YY – MM/YY)	
WELLINGTON HIGH SCHOOL		08/99-05/02	
Address	City	State	Zip
2101 GREENVIEW SHORE BLVD	WELLINGTON	FL	33414
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/25-CURRENT	[redacted]	BLUE DIAMOND	NV	[redacted]
04/21-04/25		LAS VEGAS	NV	
05/19-03/21		ROYAL PALM BEACH	FL	
12/16-04/19		WEST PALM BEACH	FL	
06/13-11/16		WELLINGTON	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
DIA-FOOT			04/21-CURRENT
Business Address	**City**	**State**	**Zip**
4280 WEST WINDMILL LN, SUITE 111	LAS VEGAS	NV	89139
Phone	**Title**	**Number of Employed Hours**	
702-970-7166	CHIEF OPERATING OFFICER	+13,000 HRS	
Description of Duties			
RESPONSIBLE FOR EXECUTIVE LEADERSHIP WITH CEO AND CFO IN OPERATING ALL ASPECTS OF THE COMPANY. CURRENT DESIGNATED REP, MDEG ADMINISTRATOR, ABC CERTIFIED PEDORTHIST FOR FACITLY.			

Business Name			From - To (MM/YY – MM/YY)
DIA-FOOT			07/20-03/21
Business Address	**City**	**State**	**Zip**
3281 FAIRLANE FARMS RD, SUITE 4	WELLINGTON	FL	33414
Phone	**Title**	**Number of Employed Hours**	
561-791-1213	FACILITY MANAGER - ASSISTANT OPERATIONS MGR	+1,200	
Description of Duties			
GENERAL OVERSIGHT OF ALL DAILY OPERATIONS WITH EMPHASIS ON COMPLIANCE, AND ENFORCING POLICIES AND PROCEDURES. RESPONSIBLE FOR THE FITTING AND DISPENSING OF DIABETIC SHOES/INSERTS			

Business Name			From - To (MM/YY – MM/YY)
NEW BALANCE SOUTH FLORIDA			11/13-10/19
Business Address	**City**	**State**	**Zip**
6000 GLADES RD, STE 1234	BOCA RATON	FL	33431
Phone	**Title**	**Number of Employed Hours**	
	MANAGER - FIT SPECIALIST	+21,000	
Description of Duties			
SEASONED RETAIL PROFESSIONAL WITH MANAGING DAILY OPERATIONS IN A FAST PACE ENVIRONMENT. SPECIALIZED IN IMPLEMENTING A ROBUST DOCTOR REFERRAL AND WELLNESS PROGRAM.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

01/15/2026
Date

I, SARA MICHELLE SIMONSON, **certify that as the MDEG Administrator for**

FOOT CARE STORE, LLC dba DIA-FOOT,

that I (initial that you have read and meet the following requirements):

1. SMS Have a high school diploma or its equivalent;
2. SMS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SMS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SMS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SARA SIMONSON

Print Name (First, Last)

Sara M. Simonson

Original Signature (electronic, copies or stamps not accepted)

01/15/2026

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler FOOT CARE STORE, LLC dba DIA-FOOT

Pharmacy/Wholesaler License # (if applicable) WH03038

Physical Address 4280 WEST WINDMILL LN, STE 111

City LAS VEGAS State NV Zip 89139

Mailing Address (if different from physical address) 3281 FAIRLANE FARMS RD

City WELLINGTON State FL Zip 33414

Telephone 561-791-1213 Website WWW.DIA-FOOT.COM

Licensing Company Email JAY@DIA-FOOT.COM

Section 2: Personal Information

First SARA Middle MICHELLE Last SIMONSON

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City BLUE DIAMOND State NV [redacted]

Telephone [redacted] Email MICHELLE@DIA-FOOT.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
PEACE COLLEGE			08/02-05/06
Address	**City**	**State**	**Zip**
15 EAST PEACE ST	RALEIGH	NC	27604
Diploma/Degree obtained, if any			
BACHELORS - BIOLOGY			

School Name			From - To (MM/YY – MM/YY)
PEACE COLLEGE			08/02-08/04
Address	**City**	**State**	**Zip**
15 EAST PEACE ST	RALEIGH	NC	27604
Diploma/Degree obtained, if any			
ASSOCIATES OF ARTS			

School Name			From - To (MM/YY – MM/YY)
WELLINGTON HIGH SCHOOL			08/99-05/02
Address	**City**	**State**	**Zip**
2101 GREENVIEW SHORE BLVD	WELLINGTON	FL	33414
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/25-CURRENT	[redacted]	BLUE DIAMOND	NV	[redacted]
04/21-04/25		LAS VEGAS	NV	
05/19-03/21		ROYAL PALM BEACH	FL	
12/16-04/19		WEST PALM BEACH	FL	
06/13-11/16		WELLINGTON	FL	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
DIA-FOOT			04/21-CURRENT	
Business Address		**City**	**State**	**Zip**
4280 WEST WINDMILL LANE, SUITE 111		LAS VEGAS	NV	89139
Phone	**Title**		**Number of Employed Hours**	
702-970-7166	CHIEF OPERATING OFFICER		+13,000 HRS	
Description of Duties				
RESPONSIBLE FOR EXECUTIVE LEADERSHIP WITH CEO AND CFO IN OPERATING ALL ASPECTS OF THE COMPANY. CURRENT DESIGNATED REP, MDEG ADMINISTRATOR, ABC CERTIFIED PEDORTHIST FOR FACILITY.				

Business Name			From - To (MM/YY – MM/YY)	
DIA-FOOT			07/20-03/21	
Business Address		**City**	**State**	**Zip**
3281 FAIRLANE FARMS RD, SUITE 4		WELLINGTON	FL	33414
Phone	**Title**		**Number of Employed Hours**	
561-791-1213	FACILITY MANAGER - ASSISTANT OPERATIONS MGR		+1,200 HRS	
Description of Duties				
GENERAL OVERSIGHT OF ALL DAILY OPERATIONS WITH EMPHASIS ON COMPLIANCE, AND ENFORCING POLICIES AND PROCEDURES. RESPONSIBILE FOR THE FITTING AND DISPENSING OF DIABETIC SHOES/INSERTS				

Business Name			From - To (MM/YY – MM/YY)	
NEW BALANCE SOUTH FLORIDA			11/13-10/19	
Business Address		**City**	**State**	**Zip**
6000 GLADES RD, STE 1234		BOCA RATON	FL	33431
Phone	**Title**		**Number of Employed Hours**	
	MANAGER - FIT SPECIALIST		+21,000	
Description of Duties				
SEASONED RETAIL PROFESSIONAL WITH MANAGING DAILY OPERATIONS IN A FAST PACE ENVIRONMENT. SPECIALIZED IN IMPLEMENTING A ROBUST DOCTOR REFERRAL AND WELLNESS PROGRAM.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

01/15/2026
Date

I, SARA MICHELLE SIMONSON, **certify that as the designated representative for**

FOOT CARE STORE, LLC dba DIA-FOOT,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SMS I am at least 21 years of age;
3. SMS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SMS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SMS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SMS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SMS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

SARA SIMONSON

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/15/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sara Simonson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/17/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Sara Simonson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/17/2026

Date

Subscribed and Sworn to before me this 17th day of January, 2026.

Notary Public Signature

Brianda Carreon
Notary Public-State of Nevada
Appointment No. 25-0391-01
My Appointment Expires 12/26/2028

(Seal)

Current Employees:

Sara Michelle Simonson

Jocelyn Tadeo Hernandez

Dazzmin Montes

10C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	■ Nevada ☐ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Howmedica Osteonics Corp. dba Stryker Orthopaedics

Physical Address: 5905 South Decatur Blvd., Suite 8

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 626 230 2608 Website: Stryker.com

Name of Designated Representative (DR): William Wakefield

Licensing Company Email: jr.licensing@stryker.com DR Email: william.wakefield@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: NO GASES	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: ASC		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Howmedica Osteonics Corp
Address: 325 Corporate Drive City: Mahwah State: NJ Zip: 07430
Name: Wright Medical Technology, Inc.
Address: 11576 Memphis Arlington Rd. City: Arlington State: TN Zip: 38002
Name: Tornier Inc.
Address: 1081 Nesbitt Ave. City: South Bloomington State: MN Zip: 55437
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Michigan
Parent Company (if any):
Corporation Name: Stryker Corporation
Mailing Address: 1941 Stryker Way
City: Portage State: MI Zip: 49002
Telephone: 269-385-2600 Email: austin.ke@stryker.com
Contact Person Name: Austin Ke
Date of SEC Registration: 1979 SEC Registration Number: 001-13149 Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NJ
Parent Company (if any): Stryker Corporation (Howmedica Osteonics Corp is wholly owned by Strker Corporation)
Corporation/Organization Name: Howmedica Osteonics Corp
Mailing Address: 325 Corporate Drive
City: Mahwah State: NJ Zip: 07430
Telephone: 973-405-0839 Email: jr.licensing@stryker.com
Contact Person Name: Jennifer Santos

Section 6: Partnership

Partnership Name: NA
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: NA
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stryker Orthopaedics

Facility Name

Jennifer Santos

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/16/25

Date

Board Use Only	Date Received: 10/21/25	Amount: $1000 cc

Entity Name: Howmedica Osteonics Corp.

Name	Title
Stiles, Spencer S.	President
Menon, Viju	Vice President

Stryker Corporation
Howmedica Osteonics Corp Organizational Structure
April 30, 2025



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **HOWMEDICA OSTEONICS CORP.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/13/2003, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 06/24/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202506245836980
You may verify this certificate online at https://www.nvsilverflume.gov/home

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to certify:

Entity Name: STRYKER CORPORATION
Entity ID#: 800151233
Entity Type: Domestic Profit Corporation
Initial Filing Date: 02/20/1946
Delayed Effective Date:
Formation Jurisdiction: Michigan
Act Formed Under: 327-1931 Michigan General Corporation Act

That the above referenced entity was validly incorporated and said corporation is validly in existence under the laws of this state.

This certificate is issued in conformity with the Act it is formed under, to attest to the fact that the company is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRES ★ Corporations, Securities & Commercial Licensing Bureau ★

In testimony whereof, I have hereunto set my hand, in the City of Lansing, on October 13, 2025.

Linda Clegg

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

Certificate Number: 30877
Verify this certificate at: www.michigan.gov/corpverifycertificate

BUSINESS LICENSE

City of Las Vegas | Las Vegas, Nevada

IN ACCORDANCE WITH THE PROVISIONS OF THE LAS VEGAS MUNICIPAL CODE, AS A[redacted]LICENSE IS HEREBY GRANT[redacted] OPERATE THE BUSINESS REFERENCED BELOW.

LICENSE #: G63-09136

RENEWAL DATE: 12/01/2019

EXPIRATION DATE: 12/01/2020

TYPE OF LICENSE: E03 - EXPRESS OR DELIVERY SERVICE
DELIVERY OF MEDICAL EQUIPMENT

BUSINESS LOCATION: 5905 S DECATUR BLVD

ISSUED TO:

WESTPAC SURGICAL LLC
15757 N 78TH ST STE B
C/O BRIAN DUDLEY
SCOTTSDALE, AZ 85260

CITY OF LAS VEGAS NEVADA

Deputy Director, Planning Department

Failure to maintain an active state license or SNHD health permit, if required, renders this business license invalid.

Post in a conspicuous place.

PM-BMD-02-18
Form 167

CLARK COUNTY BUSINESS LICENSE

LICENSE NUMBER: 2000223-424

LICENSE PERIOD: 02/01/2025 - 07/31/2025

POST IN A CONSPICUOUS PLACE AT THE BUSINESS LOCATION

ISSUED TO:
Stryker Orthopaedics
5905 S Decatur Blvd Ste 8
Las Vegas, NV 89118

BUSINESS LOCATION ADDRESS:

5905 S Decatur Blvd Ste 8
Las Vegas, NV 89118

TYPE OF LICENSE: Health/Medical Supplies

All signage must conform to standards set forth in Clark County Codes 30.72 and 30.48. Business owners are responsible to keep business property free of trash and graffiti, conform to all zoning codes requirements and, if applicable, all conditions set forth in a Notice of Final Action issued by Comprehensive Planning.

Current Planning Comments:
C-2 zone. Approved for retail sales of medical supplies.

DISCLAIMER

ISSUANCE OF A BUSINESS LICENSE IS NOT AN ENDORSEMENT OF THE BUSINESS PRACTICE OF THE LICENSEE.
PLEASE SEE REVERSE SIDE FOR ADDITIONAL INFORMATION

Vincent V. Queano

VINCENT V. QUEANO
DIRECTOR OF BUSINESS LICENSE

DEPARTMENT OF BUSINESS LICENSE
500 S GRAND CENTRAL PARKWAY
BOX 551810
LAS VEGAS NV 89155-1810
PHONE: (702) 455-4340

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 10/17/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	CONTACT NAME: PHONE (A/C. No. Ext): (312) 381-1000 FAX (A/C. No.): E-MAIL ADDRESS:
INSURED Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Old Republic Insurance Company — 24147 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** 570116277899 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY31876425	11/01/2025	11/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$500,000
							MED EXP (Any one person)	Excluded
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 318760-25	11/01/2025	11/01/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	X PhysDamage-Self In							
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31875925	11/01/2025	11/01/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH)	N/A		AOS				
A	If yes, describe under DESCRIPTION OF OPERATIONS below			MWXS31876125	11/01/2025	11/01/2026	E.L. EACH ACCIDENT	$1,000,000
				Excess WC-MI			E.L. DISEASE-EA EMPLOYEE	$1,000,000
				SIR applies per policy terms & conditions			E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier : EOCGL3MAL1MEL1M

Certificate No : 570116277899

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Howmedica Osteonics, Corp. MDEG License # (if applicable) _____

Physical Address 5905 S DECATUR BLVD STE 8

City LAS VEGAS State NV Zip 89118

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website www.stryker.com

Licensing Company Email jr.licensing@stryker.com

Section 2: Personal Information

First WILLIAM Middle CHARLES Last WAKEFIELD

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ☑ M ☐ F ☐ X

Mailing Address 5905 S DECATUR BLVD STE 8

City LAS VEGAS State NV Zip 89118

Telephon[redacted] Email WILLIAM.WAKEFIELD@STRYKER.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
COLLEGE OF SOUTHERN NEVADA		09/12- 06/13	
Address	**City**	**State**	**Zip**
700 COLLEGE DR	HENDERSON	NV	89002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
CORONADO HS		08/06 - 06/09	
Address	**City**	**State**	**Zip**
1001 CORONADO CENTER DR	HENDERSON	NV	989052
Diploma/Degree obtained, if any			
DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/1/2025- CUR	[redacted]	HENDERSON	NV	[redacted]
01/24-10/25		HENDERSON	NV	
1/23-1/24		HENDERSON	NV	
06/15- 12/22		LAKE BALBOA	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
STRYKER			03/20 - CURRENT	
Business Address		**City**	**State**	**Zip**
5905 S DECATUR BLVD STE 8		LAS VEGAS	NV	89118
Phone	**Title**		**Number of Employed Hours**	
702-521-5476	OPERATIONS/ INVENTORY TEAM LEAD		Full Time	
Description of Duties				
OPERATIONS COORDINATOR, INVENTORY ANALYST, MANAGING EMPLOYEE TIME CARDS, INVENTORY AUDITS IN THE FIELD, PROCESSING KIT AND INSTRUMENT SETS TO COMPLETION.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, WILLIAM WAKEFIELD, **certify that as the MDEG Administrator for**

Howmedica Osteonics, Corp.,

that I (initial that you have read and meet the following requirements):

1. WW Have a high school diploma or its equivalent;
2. WW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. WW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. WW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WILLIAM WAKEFIELD
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/29/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Stryker Orthopaedics

Pharmacy/Wholesaler License # (if applicable): NA

Physical Address: 5905 South Decatur Blvd Suite 8

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website: STRYKER.COM

Licensing Company Email: jr.licensing@stryker.com

Section 2: Personal Information

First: William Middle: Charles Last: Wakefield

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 5905 S Decatur BLVD suite 8

City: Las Vegas State: NV Zip: 89118

Telephone: [redacted] Email: william.wakefield@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Coronado HS		08-2005 - 06-2009	
Address	City	State	Zip
1001 Coronado Center Dr	Henderson	NV	89052
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
College of Southern Nevada		08-2012 / 06-2013	
Address	City	State	Zip
700 College Dr.	Henderson	NV	89002
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01-24 / current	[redacted]	Henderson	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
01-23 / 01-24		Henderson	NV	
From - To (MM/YY – MM/YY)		City	State	
01-2021 / 01-2023		Santa Clarita	CA	
From - To (MM/YY – MM/YY)		City	State	
01-2015 / 01-2021		Lake Balboa	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Stryker Orthopedics			02-2017 / 06-2025	
Business Address		**City**	**State**	**Zip**
5905 S Decatur BLVD suite 8		Las Vegas	NV	89118
Phone	**Title**		**Number of Employed Hours**	
702-521-5476	Team Lead		16,000	
Description of Duties				
Distribution of medical device				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic copies or stamps not accepted)

6.26.25
Date

I, William Wakefield, **certify that as the designated representative for**

Stryker Orthopedics,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WW I am at least 21 years of age;
3. WW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

WILLIAM WAKEFIELD

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/25/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WILLIAM WAKEFIELD

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/25/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, William Wakefield, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-26-25

Date

Subscribed and Sworn to before me this 26th day of June, 2025.

Notary Public Signature

ANTONIO ARPON
Notary Public, State of Nevada
No. 14-13114-1
My Appt. Exp. March 12, 2026

(Seal)

From: JR Licensing <jr.licensing@stryker.com>
Sent: Monday, December 1, 2025 2:02 PM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>; JR Licensing <jr.licensing@stryker.com>
Subject: Re: Nevada Out-of-State Wholesaler Application-Stryker Orthopaedics

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.
Hi Maria,

Attached you will find the updated COI

Below are employee names:

8745 Technology Way, Reno, NV 89502

1. Dwight Foreman
2. Ryan Mcdonald

5905 South Decatur Blvd., Las Vegas, NV 89118

1. William Wakefield
2. Errol Sapp
3. Kenneth Kammerer
4. Carlos Verde
5. Ryan McCullough
6. Butterscotch Tate
7. Butterscotch Tate II
8. Duke Becker
9. Louie Salenga

Please let me know if anything else is needed.

Jenn Santos (She/Her)
Sr. Project Associate
Stryker
Field Functional Commercial Operations
Stryker.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan		38-1239739
(State of incorporation)		(I.R.S. Employer Identification No.)
1941 Stryker Way, Portage, Michigan		49002
(Address of principal executive offices)		(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange
3.375% Notes due 2032	SYK32	New York Stock Exchange
3.625% Notes due 2036	SYK36	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $123,147,898,554 at June 30, 2024. There were 381,579,123 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2025 Annual Meeting of Shareholders (the 2025 proxy statement) are incorporated by reference into Part III.

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PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers,
we are driven
to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right.	We do what we say.	We grow talent.	We deliver.

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and artificial intelligence-assisted virtual care platform technology; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics and Spine, the Interventional Spine (IVS) portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. In addition, we changed the name of our "Orthopaedics and Spine" operating segment to "Orthopaedics."

Quarterly Net Sales - Enabling Technologies

	2024	2023	2022
Mar 31	$ 30	$ 31	$ 30
Jun 30	$ 31	$ 32	$ 25
Sep 30	$ 59	$ 54	$ 44
Dec 31	$ 32	$ 32	$ 32
Total	**$ 152**	**$ 149**	**$ 131**

Quarterly Net Sales - IVS

	2024	2023	2022
Mar 31	$ 98	$ 77	$ 65
Jun 30	$ 98	$ 83	$ 73
Sep 30	$ 117	$ 84	$ 72
Dec 31	$ 100	$ 83	$ 72
Total	**$ 413**	**$ 327**	**$ 282**

Quarterly Net Sales - Spinal Implants

	2024	2023	2022
Mar 31	$ 171	$ 176	$ 183
Jun 30	$ 178	$ 181	$ 193
Sep 30	$ 186	$ 180	$ 182
Dec 31	$ 172	$ 176	$ 175
Total	**$ 707**	**$ 713**	**$ 733**

Net Sales by Reportable Segment

	2024		2023		2022	
MedSurg and Neurotechnology	$ 13,518	60 %	$ 12,163	59 %	$ 10,893	59 %
Orthopaedics	9,077	40	8,335	41	7,556	41
Total	**$ 22,595**	**100 %**	**$ 20,498**	**100 %**	**$ 18,449**	**100 %**

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and artificial intelligence-assisted virtual care platform technology (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson MedTech (a subsidiary of Johnson & Johnson) and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson Medtech, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2024		2023		2022	
Instruments	$ 2,834	21 %	$ 2,534	21 %	$ 2,245	21 %
Endoscopy	3,389	25	3,068	25	2,759	25
Medical	3,852	28	3,459	28	3,031	28
Neurovascular	1,307	10	1,226	11	1,200	11
Neuro Cranial	2,136	16	1,876	15	1,658	15
Total	$ 13,518	100 %	$ 12,163	100 %	$ 10,893	100 %

In 2024 Instruments launched SurgiCount+ powered by Triton, which combines our existing sponge counting technology with artificial intelligence and quantifying blood loss software. We also launched CoPilot, which combines with our Spine Q guidance system to help surgeons plan and perform certain spinal procedures, including supporting bone resection, pedicle preparation and screw delivery.

In addition we completed the acquisition of Vertos Medical, Inc., a leader in interventional pain management solutions for chronic lower back pain caused by lumbar spinal stenosis. The acquisition of Vertos is complementary to our Interventional Spine business as we continue to focus on advanced pain procedures.

Endoscopy continued to deliver its 4K 1788 Camera platform to the market. Our 1788 Camera platform features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat and can be used to visualize indocyanine green and Cytalux.

Medical launched the LIFEPAK 35 monitor/defibrillator, our next generation platform designed to optimize care with new clinical features such as the new Glasgow 30.4 algorithm, cprINSIGHT, 15-lead monitoring capabilities, and STJ Insight and mapping. LIFEPAK 35 combines a modern intuitive touch screen display and increased processing power with Bluetooth and WiFi data connectivity.

Medical also completed the acquisition of care.ai, a virtual care and ambient intelligence solutions platform. care.ai adds complementary technology that is expected to integrate seamlessly with the Vocera platform (Vocera) and Stryker's devices, providing customers with an enterprise-wide ecosystem that is intended to deliver dynamic clinical workflows and further the development of smart care facilities.

Neurovascular initiated a targeted launch of the Surpass Elite Flow Diverting Stent (FDS) in the U.S. and South Korea. Surpass Elite FDS is designed to reduce thrombin generation when compared to unmodified stents. Additionally, Neurovascular launched Surpass Evolve FDS in Japan. The Stryker FDS platform is designed to effectively treat aneurysms by redirecting blood flow away from the aneurysm to promote healing.

Orthopaedics

Orthopaedics products primarily include implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technologies, products and services they need to support each patient's clinical challenge.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, Johnson & Johnson MedTech and Smith & Nephew.

Composition of Orthopaedics Net Sales

	2024		2023		2022	
Knees	$ 2,447	27 %	$ 2,273	27 %	$ 1,997	26 %
Hips	1,704	19	1,544	18	1,413	19
Trauma and Extremities	3,507	39	3,147	38	2,807	37
Spinal Implants	707	8	713	9	733	10
Other	712	8	658	8	606	8
Total	$ 9,077	100 %	$ 8,335	100 %	$ 7,556	100 %

In 2024 we continued the full commercial launch of our Triathlon Hinge revision knee system. Triathlon Hinge received approval in August of 2023 and is now released in the U.S., Canada and New Zealand. We also continued delivering growth in total hip arthroplasty, particularly in the primary segment where Direct Anterior Reconstructive Technology and Mako Total Hip can help to reduce, if not eliminate, a surgeon's use of intraoperative fluoroscopy during direct anterior hip procedures. With the acquisition of SERF SAS, we strengthened distribution in key European markets and continue to scale differentiated solutions such as the Novae monolithic dual mobility cup engineered to deliver greater hip stability and reduce dislocation risk.

We continued to expand our global footprint of Mako SmartRobotics™ in 2024 which is now sold in more than 45 countries. To date more than one million robotic Mako Total Knees and 1.5 million robotic procedures across Total Hips, Total Knees and Partial Knees have been performed globally. Stryker's Joint Replacement division also launched the "Scan. Plan. Mako Can." direct to patient campaign, accelerating awareness of Mako technology in the U.S.

Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

In December 2024 we performed our first Mako Shoulder procedure using robotic-arm assistance to remove bone, prepare the glenoid surface and enable positioning and placement of the Perform Reversed Glenoid implant.

In 2024 Trauma launched Pangea, a comprehensive variable angle plating portfolio designed to optimize plate fit to bone utilizing simple, intuitive instrumentation that enhances ease of use and reproducibility. These combined solutions empower Stryker to deliver a complete portfolio across all trauma segments.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2024 we owned approximately 5,600 United States patents and approximately 8,600 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the

summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2022, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. Any resulting investigations and prosecutions potentially carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2024 we had approximately 53,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups, which are open to all employees, to focus on creating community and belonging

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer to our executive officers.

Information about our Executive Officers

As of January 31, 2025

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	59	Chair, Chief Executive Officer and President	2011
Yin C. Becker	61	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	59	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	63	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	55	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	54	Vice President, Chief Legal Officer	2019
Viju S. Menon	57	Group President, Global Quality and Operations	2018
J. Andrew Pierce	51	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	48	Group President, Orthopaedics	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2025 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our or Inari Medical, Inc.'s ("Inari") products;
- geopolitical risks, including from international conflicts, which could, among other things, lead to increased market volatility;

- pricing pressures generally, including cost-containment measures that have adversely affected and could in the future adversely affect the price of or demand for our or Inari's products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products, including Inari products, by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in coverage and reimbursement levels from third-party payors;
- changes in the competitive environment;
- breaches, failures or other disruptions of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes, including our acquisition of Inari;
- our ability to realize any anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- uncertainties as to the timing of the tender offer for shares of Inari common stock and the subsequent merger with Inari;
- uncertainties as to how many of Inari's stockholders will tender their shares in the tender offer;
- the failure to satisfy any of the closing conditions to the acquisition of Inari, including the expiration or termination of the Hart-Scott-Rodino Antitrust Improvements Act waiting period (and the risk that such governmental approval may result in the imposition of conditions that could adversely affect the expected benefits of the transaction);
- delays in consummating the acquisition of Inari or the risk that the transaction may not close at all;
- unexpected liabilities, costs, charges or expenses in connection with the acquisition of Inari;
- the effects of the proposed Inari transaction (or the announcement thereof) on the parties' relationships with employees, customers, other business partners or governmental entities; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to the risk of product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to any raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to, among other things, the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, business disruptions, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer, possibly materially. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, in recent years, the market has experienced inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may in the future result in, high interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may in the future experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, high interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors, including changes in reimbursement practices and coverage policies and third-party payor cost containment measures: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in coverage or reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. Coverage policies and reimbursement levels can vary across the payer community globally, regionally, and locally, and may affect which products customers purchase, the market acceptance rate for new technologies and the prices customers are willing to pay for those products in a particular jurisdiction. Furthermore, any changes to the coverage or reimbursement landscape, or adverse decisions relating to our products by administrators of these systems could significantly reduce reimbursement for procedures using our products or result in denial of reimbursement for those products, which could adversely affect customer demand, or the price customers are willing to pay for such products. Public and private payers have challenged, and are expected to continue to challenge, prices charged for medical products and services. Such downward pricing pressures from any or all of these payers may result in an adverse effect on our business, results of operations, financial condition and cash flows. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition and the regulatory burden in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation, new product development and improvement of existing products. New business models, products and surgical procedures, as well as improvements to existing products, are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, including by our existing competitors and new market entrants, which could adversely impact demand for certain of our existing products. The success of our products and services depends on, among other things, our ability to properly identify customer needs and predict future needs; innovate and develop new technologies, services and applications at an accelerated pace; and appropriately allocate our research and development spending to products and services with higher growth. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We work with healthcare professionals in a transparent and responsible manner and seek to maintain these relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in coverage or reimbursement levels from third-party payors in the United States and other countries; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with

the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability and uncertainty; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which has increased the risks we are subject to.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Furthermore, numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Emerging technologies such as generative artificial intelligence (AI) may be used by malicious actors to create more targeted phishing narratives, spread disinformation about us or our products or otherwise strengthen social engineering capabilities. Some of our products, services, and information technology systems contain or use open-source software which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, unauthorized access to, and disruptions of, products or systems. While such breaches, unauthorized access and disruptions have not had a material effect on us to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity or other technology related incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment and customer requirements related to information security, data collection and use, and privacy become increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability.

Hardware and software failures or delays in our key information technology systems, networks, processes or sites could disrupt our operations, cause the loss of confidential information or otherwise adversely impact our business. Our systems, networks, processes and sites may be vulnerable to damage, disruptions and shutdown from a variety of sources, including malfunctions in maintenance updates or security patches, design defects, the age of the technology, network failures, modernization or other initiatives, human acts and natural disasters. For example, some of our information technology systems contain legacy third-party software components for which we depend on a layered security

approach to protect against exploitation, which may not be effective. Any such damage or disruptions could also compromise the security of our information systems and networks. These issues can also arise as a result of failures by, or in the software or hardware of, third parties, including networks or service providers, with whom we do business and over whom we have limited or no control. Any disruption or failure of our systems, networks, processes or sites could have a material impact on our business and operations.

If our IT systems, networks or processes are damaged or cease to function properly for any reason, the networks, service providers, hardware or software we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive workforce in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by

governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. It is not possible to predict whether elective medical procedures will be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and may continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm, among other things.

Our use of AI and other emerging technologies could adversely impact our business and financial results: We have begun to deploy AI and other emerging technologies in various facets of our operations and we continue to explore further use cases. The rapid advancement of these technologies presents opportunities for us in research, manufacturing, commercialization, and other business endeavors, but also entails risks, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. In addition, any disruption or failure in the AI functionality we incorporate into our business activities, products or services could adversely impact our business or result in delays or errors in our product offerings. The legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity and privacy and data protection. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant costs on us and limit our ability to effectively develop, deploy or use AI technologies. Furthermore, if we are unable to effectively manage the use of AI technologies by our employees and service providers, our confidential information, intellectual property and reputation could be put at risk. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with prior pandemics, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks that revise the existing profit allocation and nexus rules (Pillar 1) and ensure a minimal level of taxation (Pillar 2), respectively. In 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws are effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes, could increase tax expense in future periods.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to healthcare or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. Both in the U.S. and internationally, governmental authorities may make legislative or administrative reforms to existing reimbursement programs, make adverse decisions relating to our

products' coverage or reimbursement, or make changes to patient access to healthcare, all of which could adversely impact the demand for and usage of our products or the prices that our customers are willing to pay for them. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. For example, governmental authorities in the United States and internationally have or are considering adopting regulations on the use of per- and polyfluoroalkyl substances. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We may also be subject to legal obligations in some countries that require disclosure or sharing of proprietary information. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws have in the past resulted and could in the future result in investigations, litigation or government proceedings, and we have been and may in the future be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. For example, in 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and enforcement and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial

Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive) mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The European Product Liability Directive was revised in 2024 and will become fully adopted into each member state's national laws by 2026. The revised Product Liability Directive and Collective Redress Directive exposes us to additional litigation risks and could result in significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on intellectual proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents and the expiration of patents may lead to a loss of exclusive rights and/or increased competition.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties, financing transactions in currencies other than the United States Dollar and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars. In recent years, currency exchange rates have been especially volatile, and these currency fluctuations have affected, and may continue to affect, our results of operations.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve, including in diverging directions. On occasion, we announce new initiatives and make disclosures, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest and applicable regulatory requirements, which include environment and sustainability, workforce-related issues, diversity, equity and inclusion and supply chain management, among others. Implementation of these initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in, among other things, reduced demand for our products, reduced profits, increased investigations and litigation and an increased risk of reputational damage. If we are unable to satisfy evolving criteria, certain investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate or undesirable. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change have increased and are expected to further increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures and flooding, which could cause more significant business and supply chain

interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors periodically. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 27 company-owned and 297 leased locations worldwide including 45 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products.

We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various ongoing proceedings, legal actions and claims arising in the normal course of our business, including proceedings related to product, labor, intellectual property and other matters. Refer to Note 7 to our Consolidated Financial Statements for further information.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2025 there were 2,510 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2024 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2024 was $1,033.

In the fourth quarter 2024 we did not issue shares of our common stock as performance incentive awards to employees. When issued, these shares are not registered under the Securities Act of 1933 based on the conclusion that the awards are not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2019 in our common stock and each of the indices.

COMPARISON OF CUMULATIVE FIVE YEAR TOTAL RETURN



Company / Index	2019	2020	2021	2022	2023	2024
Stryker Corporation	**$ 100.00**	**$ 118.17**	**$ 130.25**	**$ 120.59**	**$ 149.29**	**$ 181.15**
S&P 500 Index	$ 100.00	$ 118.40	$ 152.39	$ 124.79	$ 157.59	$ 197.02
S&P 500 Health Care Index	$ 100.00	$ 113.45	$ 143.09	$ 140.29	$ 143.18	$ 146.87

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2024	2023	2022	2021	2020
Net sales	$ 22,595	$ 20,498	$ 18,449	$ 17,108	$ 14,351
Cost of sales	8,155	7,440	6,871	6,140	5,294
Gross profit	$ 14,440	$ 13,058	$ 11,578	$ 10,968	$ 9,057
Research, development and engineering expenses	1,466	1,388	1,454	1,235	984
Selling, general and administrative expenses	7,685	7,111	6,386	6,266	5,163
Amortization of intangible assets	623	635	627	619	472
Goodwill and other impairments	977	36	270	264	215
Total operating expenses	$ 10,751	$ 9,170	$ 8,737	$ 8,384	$ 6,834
Operating income	$ 3,689	$ 3,888	$ 2,841	$ 2,584	$ 2,223
Other income (expense), net	(197)	(215)	(158)	(303)	(269)
Earnings before income taxes	$ 3,492	$ 3,673	$ 2,683	$ 2,281	$ 1,954
Income taxes	499	508	325	287	355
Net earnings	$ 2,993	$ 3,165	$ 2,358	$ 1,994	$ 1,599
Net earnings per share of common stock:					
Basic	$ 7.86	$ 8.34	$ 6.23	$ 5.29	$ 4.26
Diluted	$ 7.76	$ 8.25	$ 6.17	$ 5.21	$ 4.20
Dividends declared per share of common stock	$ 3.240	$ 3.050	$ 2.835	$ 2.585	$ 2.355
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,743	$ 3,053	$ 1,928	$ 3,019	$ 3,024
Accounts receivable, net	3,987	3,765	3,565	3,022	2,701
Inventories	4,774	4,843	3,995	3,314	3,494
Property, plant and equipment, net	3,448	3,215	2,970	2,833	2,752
Total assets	$ 42,971	$ 39,912	$ 36,884	$ 34,631	$ 34,330
Accounts payable	1,679	1,517	1,413	1,129	810
Total debt	13,597	12,995	13,048	12,479	13,991
Shareholders' equity	$ 20,634	$ 18,593	$ 16,616	$ 14,877	$ 13,084
Cash Flow Data					
Net cash provided by operating activities	$ 4,242	$ 3,711	$ 2,624	$ 3,263	$ 3,277
Purchases of property, plant and equipment	755	575	588	525	487
Depreciation	427	393	371	371	340
Acquisitions, net of cash acquired	1,628	390	2,563	339	4,222
Amortization of intangible assets	623	635	627	619	472
Payments of dividends	1,219	1,139	1,051	950	863
Repurchase of common stock	—	—	—	—	—
Other Data					
Number of shareholders of record	2,520	2,518	2,533	2,551	2,597
Approximate number of employees	53,000	52,000	51,000	46,000	43,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Overview of 2024

In 2024 we achieved reported net sales growth of 10.2%. Excluding the impact of acquisitions and divestitures, sales grew 10.2% in constant currency. We reported net earnings of $2,993 and net earnings per diluted share of $7.76. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,700 and adjusted net earnings per diluted share[1] of $12.19 representing growth of 15.0%.

We continued our capital allocation strategy by investing $1,628 in acquisitions and paying $1,219 in dividends to our shareholders.

In 2024 we completed various acquisitions for total consideration of $1,628 in upfront payments, net of cash acquired, as well as $400 of contingent consideration if certain commercial or clinical milestones are achieved. Refer to Note 6 to our Consolidated Financial Statements for further information.

In May 2024 we repaid the outstanding $600 principal amount of the 3.375% senior unsecured notes due May 15, 2024. In September 2024 we issued $750 of 4.250% senior unsecured notes due September 11, 2029, €800 of 3.375% senior unsecured notes due September 11, 2032, $750 of 4.625% senior unsecured notes due September 11, 2034 and €600 of 3.625% senior unsecured notes due September 11, 2036. In November 2024 we repaid the outstanding €500 of floating rate senior notes and in December 2024 we repaid €850 of 0.250% senior unsecured notes.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2024	2023	2022	2024	2023	2022	2024 vs. 2023	2023 vs. 2022
Net sales	$ 22,595	$ 20,498	$ 18,449	100.0 %	100.0 %	100.0 %	10.2 %	11.1 %
Gross profit	14,440	13,058	11,578	63.9	63.7	62.8	10.6	12.8
Research, development and engineering expenses	1,466	1,388	1,454	6.5	6.8	7.9	5.6	(4.5)
Selling, general and administrative expenses	7,685	7,111	6,386	34.0	34.7	34.6	8.1	11.4
Amortization of intangible assets	623	635	627	2.8	3.1	3.4	(1.9)	1.3
Goodwill and other impairments	977	36	270	4.3	0.2	1.5	nm	nm
Other income (expense), net	(197)	(215)	(158)	(0.9)	(1.0)	(0.9)	(8.4)	36.1
Income taxes	499	508	325	nm	nm	nm	(1.8)	56.3
Net earnings	$ 2,993	$ 3,165	$ 2,358	13.2 %	15.4 %	12.8 %	(5.4)%	34.2 %
Net earnings per diluted share	$ 7.76	$ 8.25	$ 6.17				(5.9)%	33.7 %
Adjusted net earnings per diluted share[1]	$ 12.19	$ 10.60	$ 9.34				15.0 %	13.5 %

nm - not meaningful

Geographic and Segment Net Sales

				Percentage Change			
				2024 vs. 2023		2023 vs. 2022	
	2024	2023	2022	As Reported	Constant Currency	As Reported	Constant Currency
Geographic:							
United States	$ 16,943	$ 15,257	$ 13,638	11.0 %	11.0 %	11.9 %	11.9 %
International	5,652	5,241	4,811	7.9	9.8	8.9	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %
Segment:							
MedSurg and Neurotechnology	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	11.7 %	12.2 %
Orthopaedics	9,077	8,335	7,556	8.9	9.4	10.3	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %

Supplemental Net Sales Growth Information

				Percentage Change									
				2024 vs. 2023					2023 vs. 2022				
						United States	International				United States	International	
	2024	2023	2022	As Reported	Constant Currency	As Reported	As Reported	Constant Currency	As Reported	Constant Currency	As Reported	As Reported	Constant Currency
MedSurg and Neurotechnology:													
Instruments	$ 2,834	$ 2,534	$ 2,245	11.9 %	12.1 %	12.5 %	9.5 %	10.6 %	12.9 %	13.0 %	13.5 %	10.4 %	11.8 %
Endoscopy	3,389	3,068	2,758	10.5	11.0	11.1	7.7	10.7	11.2	11.7	11.9	8.0	9.9
Medical	3,852	3,458	3,031	11.4	11.7	14.6	(2.0)	(0.3)	14.1	14.4	15.0	10.7	12.3
Neurovascular	1,307	1,226	1,200	6.6	8.2	4.7	7.9	10.5	2.2	4.0	8.3	(1.5)	1.5
Neuro Cranial	2,136	1,876	1,658	13.9	14.1	15.0	8.7	10.2	13.1	13.4	12.7	15.4	16.8
	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	12.7 %	5.9 %	7.9 %	11.7 %	12.2 %	13.1 %	7.2 %	9.2 %
Orthopaedics:													
Knees	$ 2,447	$ 2,273	$ 1,997	7.6 %	8.2 %	6.7 %	10.4 %	12.2 %	13.8 %	14.4 %	12.3 %	18.5 %	20.9 %
Hips	1,704	1,544	1,413	10.3	11.3	7.2	15.9	18.4	9.3	10.4	10.3	7.5	10.7
Trauma and Extremities	3,507	3,147	2,807	11.4	11.6	12.6	8.3	9.1	12.1	12.2	12.9	10.1	10.5
Spinal Implants	707	713	733	(0.7)	(0.3)	(2.1)	2.5	3.8	(2.7)	(2.0)	(2.2)	(4.1)	(3.4)
Other	712	658	606	8.1	9.6	7.3	10.1	15.4	8.6	9.5	2.9	25.8	32.3
	$ 9,077	$ 8,335	$ 7,556	8.9 %	9.4 %	8.4 %	10.2 %	12.0 %	10.3 %	10.9 %	10.0 %	11.1 %	13.1 %
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.0 %	7.9 %	9.8 %	11.1 %	11.6 %	11.9 %	8.9 %	10.9 %

Note: In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics, the interventional spine portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. Neuro Cranial includes sales related to interventional spine of $413, $327 and $282 for 2024, 2023 and 2022. Other Orthopaedics includes sales related to Enabling Technologies of $152, $149 and $131 for 2024, 2023 and 2022. In the first quarter 2024 a product line previously included in Instruments has been reclassified to Endoscopy to align with a change in our internal reporting structure. We have reflected these changes in all historical periods presented.

Consolidated Net Sales

Consolidated net sales in 2024 increased 10.2% as reported and 10.7% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.5% impact of acquisitions and divestitures, net sales in constant currency increased by 9.1% from increased unit volume and 1.1% due to higher prices. The unit volume increase was primarily due to higher shipments across all businesses.

Consolidated net sales in 2023 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 10.9% from increased unit volume and 0.6% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses and most Orthopaedics businesses.

MedSurg and Neurotechnology Net Sales

MedSurg and Neurotechnology net sales in 2024 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.4% impact of acquisitions and divestitures, net sales in constant currency increased by 9.5% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

MedSurg and Neurotechnology net sales in 2023 increased 11.7% as reported and 12.2% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.3% impact of acquisitions and divestitures, net sales in constant currency increased by 10.2% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

Orthopaedics Net Sales

Orthopaedics net sales in 2024 increased 8.9% as reported and 9.4% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.7% impact of acquisitions and divestitures, net sales in constant currency increased by 8.7% from increased unit volume. The unit volume increase was due to higher shipments across all Orthopaedics businesses.

Orthopaedics net sales in 2023 increased 10.3% as reported and 10.9% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.6%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 11.9% from increased unit volume partially offset by 1.1% due to lower prices. The unit volume increase was due to higher shipments across most Orthopaedics businesses.

Gross Profit

Gross profit was $14,440, $13,058 and $11,578 in 2024, 2023, and 2022. The key components of the change were:

	Gross Profit Percent Net Sales
2022	**62.8 %**
Sales pricing	20 bps
Volume and mix	100 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	10 bps
2023	**63.7 %**
Sales pricing	40 bps
Volume and mix	60 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	(20) bps
Structural optimization and other special charges	(20) bps
2024	**63.9 %**

Gross profit as a percentage of net sales increased to 63.9% in 2024 from 63.7% in 2023 due to higher sales pricing and favorable volume partially offset by higher manufacturing and supply chain costs primarily due to inflationary pressures impacting fixed and variable manufacturing costs as well as higher amortization of inventory stepped up to fair value.

Gross profit as a percentage of net sales increased to 63.7% in 2023 from 62.8% in 2022 due to higher sales pricing and favorable volume offset by higher manufacturing and supply chain costs primarily due to higher raw material costs in the first six months of 2023 and supply chain inefficiencies.

While segment mix was not a significant driver of the change in gross profit as a percent of net sales between 2024, 2023 and 2022, we generally expect segment mix to have an unfavorable impact for the foreseeable future as we anticipate more rapid sales growth in our lower gross margin MedSurg and Neurotechnology segment than our Orthopaedics segment.

Research, Development and Engineering Expenses

Research, development and engineering expenses as a percentage of net sales in 2024 decreased to 6.5% from 6.8% in 2023 primarily due to lower spend on medical device regulations in the European Union.

Research, development and engineering expenses as a percentage of net sales in 2023 decreased to 6.8% from 7.9% in 2022 primarily due to increased spending for product launches, the write-off of certain intangible assets and higher spend related to the new medical device regulations in the European Union in 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses as a percentage of net sales in 2024 decreased to 34.0% from 34.7% in 2023 primarily due to continued spend discipline and lower charges for structural optimization and certain legal matters partially offset by higher acquisition-related costs.

Selling, general and administrative expenses as a percentage of net sales in 2023 of 34.7% remained relatively flat with 34.6% in 2022 as charges of $132 related to share-based awards for Vocera employees that vested upon our acquisition in 2022 were partially offset by disciplined increases in spend and investments in 2023 to support our growth, including sales growth incentives and increased spend on travel and meetings. In addition, in 2022 we determined that certain commercial and regulatory milestones related to technology acquired in the purchase of Mobius Imaging and Cardan Robotics were no longer probable of being achieved and recorded $110 to reduce the fair value of contingent consideration.

Amortization of Intangible Assets

Amortization of intangible assets was $623, $635 and $627 in 2024, 2023 and 2022. These amounts include amortization related to intangible assets acquired in 2024 from various acquisitions, 2023 from Cerus Endovascular Limited (Cerus) and 2022 from Vocera. Refer to Notes 6 and 8 to our Consolidated Financial Statements for further information.

Goodwill and Other Impairments

In 2024 and 2022 we recorded goodwill impairment charges of $456 and $216 related to our Spine business.

In 2024 we recognized an estimated loss of $362 as a result of classifying certain assets in our Spinal Implants business as held for sale. Refer to Notes 8, 16 and 17 to our Consolidated Financial Statements for further information.

In 2024, 2023 and 2022 we recorded other impairments of $159, $36 and $54. Refer to Notes 15 and 16 to our Consolidated Financial Statements for further information.

Operating Income

Operating income was $3,689, $3,888 and $2,841 in 2024, 2023 and 2022. Operating income decreased as a percentage of sales to 16.3% in 2024 from 19.0% in 2023 and increased from 15.4% in 2022. Refer to the comments above for discussion of the primary drivers of the change.

MedSurg and Neurotechnology operating income as a percentage of net sales increased to 29.6% in 2024 from 28.5% in 2023. MedSurg and Neurotechnology operating income as a percentage of net sales increased to 28.5% in 2023 from 26.0% in 2022. Orthopaedics operating income as a percentage of net sales increased to 28.5% in 2024 from 27.2% in 2023. Orthopaedics operating income as a percentage of net sales increased to 27.2% in 2023 from 29.1% in 2022. The key components of the change were:

	Operating Income Percent Net Sales	
	MedSurg and Neurotechnology	Orthopaedics
2022	**26.0 %**	**29.1 %**
Sales pricing	70 bps	(30) bps
Volume	100 bps	80 bps
Manufacturing and supply chain costs	90 bps	(220) bps
Research, development and engineering expenses	50 bps	20 bps
Selling, general and administrative expenses	(60) bps	(40) bps
2023	**28.5 %**	**27.2 %**
Sales pricing	70 bps	0 bps
Volume	40 bps	70 bps
Manufacturing and supply chain costs	(40) bps	(20) bps
Research, development and engineering expenses	0 bps	10 bps
Selling, general and administrative expenses	40 bps	70 bps
2024	**29.6 %**	**28.5 %**

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2024 from 2023 was primarily driven by higher unit volumes, higher prices and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2023 from 2022 was primarily driven by higher unit volumes, higher prices and lower manufacturing and supply chain costs due to supply chain challenges impacting capital products in our MedSurg businesses in 2022 which improved in 2023 partially offset by higher selling, general and administrative expenses as a percentage of sales due to continued investments including sales growth incentives and a more normalized cadence of travel and meetings.

The increase in Orthopaedics operating income as a percentage of net sales for 2024 from 2023 was primarily driven by higher sales volumes and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The decrease in Orthopaedics operating income as a percentage of net sales for 2023 from 2022 was primarily driven by higher higher manufacturing and supply chain costs primarily due to increased inventory reserves partially offset by higher unit volumes.

Other Income (Expense), Net

Other income (expense), net was ($197), ($215) and ($158) in 2024, 2023 and 2022. The decrease in net expense in 2024 from 2023 was primarily due to higher interest income partially offset by lower interest expense in 2024. The increase in net expense in 2023 from 2022 was primarily due to the release of accrued interest of $50 in 2022 related to the effective settlement of the United States federal income tax audit for years 2014 through 2018. Refer to Note 11 to our Consolidated Financial Statements for further information and higher interest income in 2023.

Income Taxes

Our effective tax rate was 14.3%, 13.8% and 12.1% for 2024, 2023 and 2022. The effective income tax rate for 2024 decreased from 2023 due to the 2024 deferred tax benefit on the outside basis difference related to the anticipated sale of the Spinal Implants business partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. The effective income tax rate for 2023 increased from 2022 due to the 2022 effective settlement of the United States federal income tax audit for years 2014 through 2018 and the 2022 reversal of deferred income tax on undistributed earnings of foreign subsidiaries partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. Additionally, the effective income tax rates for 2024, 2023 and 2022 reflect the continued lower effective income tax rates as a result of our European operations and certain discrete tax items.

The Organisation for Economic Cooperation and Development (OECD), which represents a coalition of member countries, has put forth two proposed base erosion and profit shifting frameworks that revise the existing profit allocation and nexus rules (Pillar One) and ensure a minimal level of taxation (Pillar Two). On December 12, 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws became effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes could increase tax expense in future periods.

Net Earnings

Net earnings for 2024 increased to $2,993 or $7.76 per diluted share from $3,165 or $8.25 per diluted share in 2023 and $2,358 or $6.17 per diluted share in 2022. Refer to the comments above for discussion of the primary drivers of the change.

Non-GAAP Financial Measures

We supplement the reporting of our financial information determined under accounting principles generally accepted in the United States (GAAP) with certain non-GAAP financial measures, including percentage sales growth in constant currency; percentage organic sales growth; adjusted gross profit; adjusted selling, general and administrative expenses; adjusted research, development and engineering expenses; adjusted operating income; adjusted other income (expense), net; adjusted income taxes; adjusted effective income tax rate; adjusted net earnings; and adjusted net earnings per diluted share (Diluted EPS). We believe these non-GAAP financial measures provide meaningful information to assist investors and shareholders in understanding our financial results and assessing our prospects for future performance. Management believes percentage sales growth in constant currency and the other adjusted measures described above are important indicators of our operations because they exclude items that may not be indicative of or are unrelated to our core operating results and provide a baseline for analyzing trends in our underlying businesses. Management uses these non-GAAP financial measures for reviewing the operating results of reportable business segments and analyzing potential future business trends in connection with our budget process and bases certain management incentive compensation on these non-GAAP financial measures. To measure percentage sales growth in constant currency, we remove the impact of changes in foreign currency exchange rates that affect the comparability and trend of sales. Percentage sales growth in constant currency is calculated by translating current and prior year results at the same foreign currency exchange rate. To measure percentage organic sales growth, we remove the impact of changes in foreign currency exchange rates, acquisitions and divestitures, which affect the comparability and trend of sales. Percentage organic sales growth is calculated by translating current year and prior year results at the same foreign currency exchange rates excluding the impact of acquisitions and divestitures. To measure earnings performance on a consistent and comparable basis, we exclude certain items that affect the comparability of operating results and the trend of earnings. The income tax effect of each adjustment was determined based on the tax effect of the jurisdiction in which the related pre-tax adjustment was recorded. These adjustments are irregular in timing and may not be indicative of our past and future performance. The following are examples of the types of adjustments that may be included in a period:

1. *Acquisition and integration-related costs.* Costs related to integrating recently acquired businesses (e.g., costs associated with the termination of sales relationships, employee retention and workforce reductions, manufacturing integration costs and other integration-related activities), changes in the fair value of contingent consideration, amortization of inventory stepped-up to fair value, specific costs (e.g., deal costs and costs associated with legal entity rationalization) related to the consummation of the acquisition process and legal entity rationalization and acquisition-related tax items.
2. *Amortization of purchased intangible assets.* Periodic amortization expense related to purchased intangible assets.
3. *Structural optimization and other special charges.* Costs associated with employee retention and workforce reductions, the closure or transfer of manufacturing and other facilities (e.g., site closure costs, contract termination costs and redundant employee costs during the work transfers), product line exits (primarily inventory, long-lived asset and specifically-identified intangible asset write-offs), certain long-lived and intangible asset write-offs and impairments and other charges.
4. *Medical device regulations.* Costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the new medical device reporting regulations and other requirements of the European Union.
5. *Recall-related matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve the Rejuvenate, LFIT V40, Wright legacy hip products and other product recalls.
6. *Regulatory and legal matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters

and the amount of favorable awards from settlements.

7. *Tax matters*. Impact of accounting for certain significant and discrete tax items.

Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names. These adjusted financial measures should not be considered in isolation or as a substitute for reported sales growth, gross profit, selling, general and administrative expenses, research, development and engineering expenses, operating income, other income (expense), net, income taxes, effective income tax rate, net earnings and net earnings per diluted share, the most directly comparable GAAP financial measures. These non-GAAP financial measures are an additional way of viewing aspects of our operations when viewed with our GAAP results and the reconciliations to corresponding GAAP financial measures at the end of the discussion of Consolidated Results of Operations below. We strongly encourage investors and shareholders to review our financial statements and publicly-filed reports in their entirety and not to rely on any single financial measure.

The weighted-average diluted shares outstanding used in the calculation of adjusted net earnings per diluted share are the same as those used in the calculation of reported net earnings per diluted share for the respective period.

Reconciliation of the Most Directly Comparable GAAP Financial Measure to Non-GAAP Financial Measure

2024	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 14,440	$ 7,685	$ 1,466	$ 3,689	$ (197)	$ 499	$ 2,993	14.3 %	$ 7.76
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	46	—	—	46	—	12	34	0.2	0.09
Other acquisition and integration-related (a)	—	(107)	(1)	108	—	23	85	0.2	0.22
Amortization of purchased intangible assets	—	—	—	623	—	128	495	1.0	1.28
Structural optimization and other special charges (b)	59	(77)	(2)	138	1	29	110	0.3	0.29
Goodwill and other impairments (c)	—	—	—	977	—	125	852	(0.6)	2.21
Medical device regulations (d)	9	—	(49)	58	—	14	44	0.1	0.11
Recall-related matters (e)	11	(29)	—	40	—	10	30	0.1	0.08
Regulatory and legal matters (f)	—	(36)	—	36	—	7	29	0.1	0.08
Tax matters (g)	—	—	—	—	—	(28)	28	(0.9)	0.07
Adjusted	$ 14,565	$ 7,436	$ 1,414	$ 5,715	$ (196)	$ 819	$ 4,700	14.8 %	$ 12.19

2023	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 13,058	$ 7,111	$ 1,388	$ 3,888	$ (215)	$ 508	$ 3,165	13.8 %	$ 8.25
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	—	—	—	—	—	—	—	—	—
Other acquisition and integration-related (a)	—	(20)	—	20	—	(25)	45	(0.8)	0.12
Amortization of purchased intangible assets	—	—	—	635	—	132	503	1.2	1.31
Structural optimization and other special charges (b)	39	(130)	(1)	170	—	38	132	0.4	0.34
Goodwill and other impairments (c)	—	—	—	36	—	9	27	0.1	0.08
Medical device regulations (d)	2	—	(94)	96	—	22	74	0.2	0.19
Recall-related matters (e)	—	(18)	—	18	—	4	14	—	0.04
Regulatory and legal matters (f)	—	(92)	—	92	—	29	63	0.4	0.16
Tax matters (g)	—	—	—	—	(8)	(51)	43	(1.2)	0.11
Adjusted	$ 13,099	$ 6,851	$ 1,293	$ 4,955	$ (223)	$ 666	$ 4,066	14.1 %	$ 10.60

2022	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 11,578	$ 6,386	$ 1,454	$ 2,841	$ (158)	$ 325	$ 2,358	12.1 %	$ 6.17
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	12	—	—	12	—	3	9	—	0.02
Other acquisition and integration-related (a)	—	(138)	—	138	—	34	104	0.6	0.27
Amortization of purchased intangible assets	—	—	—	627	—	132	495	1.7	1.30
Structural optimization and other special charges (b)	56	(152)	(87)	295	—	61	234	0.8	0.61
Goodwill and other impairments (c)	—	—	—	270	—	5	265	(1.2)	0.70
Medical device regulations (d)	3	—	(137)	140	—	25	115	0.2	0.30
Recall-related matters (e)	—	15	—	(15)	—	(3)	(12)	—	(0.03)
Regulatory and legal matters (f)	—	(76)	—	76	—	7	69	(0.2)	0.18
Tax matters (g)	—	—	—	—	(75)	(9)	(66)	0.1	(0.18)
Adjusted	$ 11,649	$ 6,035	$ 1,230	$ 4,384	$ (233)	$ 580	$ 3,571	14.1 %	$ 9.34

(a) Charges represent certain acquisition and integration-related costs associated with acquisitions, including:

	2024	2023	2022
Termination of sales relationships	$ 4	$ 5	$ 21
Employee retention and workforce reductions	22	6	33
Changes in the fair value of contingent consideration	8	(1)	(135)
Manufacturing integration costs	3	2	32
Stock compensation payments upon a change in control	22	—	132
Other integration-related activities	49	8	55
Adjustments to Operating Income	**$ 108**	**$ 20**	**$ 138**
Charges for acquisition-related tax provisions	—	—	—
Other income taxes related to acquisition and integration-related costs	23	(25)	34
Adjustments to Income Taxes	**$ 23**	**$ (25)**	**$ 34**
Adjustments to Net Earnings	**$ 85**	**$ 45**	**$ 104**

(b) Structural optimization and other special charges represent the costs associated with:

	2024	2023	2022
Employee retention and workforce reductions	$ 23	$ 69	$ 74
Closure/transfer of manufacturing and other facilities	31	50	83
Product line exits	37	22	34
Termination of sales relationships	8	—	—
Other charges	39	29	104
Adjustments to Operating Income	**$ 138**	**$ 170**	**$ 295**
Adjustments to Other Income (Expense), Net	**$ 1**	**$ —**	**$ —**
Adjustments to Income Taxes	**$ 29**	**$ 38**	**$ 61**
Adjustments to Net Earnings	**$ 110**	**$ 132**	**$ 234**

(c) Goodwill and other impairments represent the costs associated with:

	2024	2023	2022
Goodwill impairments	$ 456	$ —	$ 216
Certain long-lived and intangible asset write-offs and impairments	466	26	8
Product line exits (e.g., long-lived asset and specifically-identified intangible asset write-offs)	55	10	46
Adjustments to Operating Income	**$ 977**	**$ 36**	**$ 270**
Adjustments to Income Taxes	**$ 125**	**$ 9**	**$ 5**
Adjustments to Net Earnings	**$ 852**	**$ 27**	**$ 265**

(d) Charges represent the costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the medical device reporting regulations and other requirements of the new medical device regulations in the European Union.

(e) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain recall-related matters.

(f) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters and the amount of favorable awards from settlements.

(g) Benefits / (charges) represent the accounting impact of certain significant and discrete tax items, including:

	2024	2023	2022
Adjustments related to the transfer of certain intellectual properties between tax jurisdictions	$ (185)	$ (89)	$ (182)
Certain tax audit settlements	(1)	24	162
Reversal of deferred income tax on undistributed earnings of foreign subsidiaries	—	—	71
Deferred tax benefit on outside basis related to the anticipated sale of the Spinal Implants business	170	—	—
Other significant and discrete tax items	(12)	14	(60)
Adjustments to Income Taxes	**$ (28)**	**$ (51)**	**$ (9)**
Benefits for certain tax audit settlements	—	(9)	(45)
Other tax related adjustments	—	1	(30)
Adjustments to Other Income (Expense), Net	**$ —**	**$ (8)**	**$ (75)**
Adjustments to Net Earnings	**$ 28**	**$ 43**	**$ (66)**

FINANCIAL CONDITION AND LIQUIDITY

Net cash provided by (used in):	2024	2023	2022
Operating activities	$ 4,242	$ 3,711	$ 2,624
Investing activities	(3,000)	(992)	(2,924)
Financing activities	(525)	(1,594)	(749)
Effect of exchange rate changes	(36)	(28)	(51)
Change in cash and cash equivalents	**$ 681**	**$ 1,127**	**$ (1,100)**

We believe our financial condition continues to be of high quality, as evidenced by our ability to generate substantial cash from operations and to readily access capital markets at competitive rates despite the current macroeconomic environment. Operating cash flow provides the primary source of cash to fund operating needs and capital expenditures. Excess operating cash is used first to fund acquisitions to complement our portfolio of businesses. Other discretionary uses include dividends and share repurchases. We supplement operating cash flow with debt to fund our activities as necessary. Our overall cash position reflects our business results and a global cash management strategy that takes into account liquidity management, economic factors and tax considerations.

Operating Activities

Cash provided by operating activities was $4,242, $3,711 and $2,624 in 2024, 2023 and 2022. The increase in 2024 was primarily due to higher cash earnings partially offset by changes in working capital. The increase in 2023 from 2022 was primarily due to higher net earnings and increased collections on accounts receivable.

10D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	■ Nevada ☐ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Howmedica Osteonics Corp. dba Stryker Orthopaedics

Physical Address: 8745 Technology Way Unit B

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 916-747-1682 Website: Stryker.com

Name of Designated Representative (DR): Dwight Foreman

Licensing Company Email: jr.licensing@stryker.com DR Email: dwight.foreman@stryker.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: NO GASES	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: ASC		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Howmedica Osteonics Corp
Address: 325 Corporate Drive City: Mahwah State: NJ Zip: 07430
Name: Wright Medical Technology, Inc.
Address: 11576 Memphis Arlington Rd. City: Arlington State: TN Zip: 38002
Name: Tornier Inc.
Address: 1081 Nesbitt Ave. City: South Bloomington State: MN Zip: 55437
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Michigan
Parent Company (if any):
Corporation Name: Stryker Corporation
Mailing Address: 1941 Stryker Way
City: Portage State: MI Zip: 49002
Telephone: 269-385-2600 Email: austin.ke@stryker.com
Contact Person Name: Austin Ke
Date of SEC Registration: 1979 SEC Registration Number: 001-13149 Stock Exchange Symbol: SYK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NJ
Parent Company (if any): Stryker Corporation (Howmedica Osteonics Corp is wholly owned by Strker Corporation)
Corporation/Organization Name: Howmedica Osteonics Corp
Mailing Address: 325 Corporate Drive
City: Mahwah State: NJ Zip: 07430
Telephone: 973-405-0839 Email: jr.licensing@stryker.com
Contact Person Name: Jennifer Santos

Section 6: Partnership

Partnership Name: NA
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: NA
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Stryker Orthopaedics

Facility Name

Jennifer Santos

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/16/25

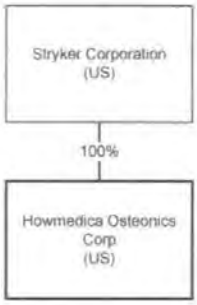
Date

Board Use Only	Date Received: 10/21/25	Amount: $1000cc ✓

Entity Name: Howmedica Osteonics Corp.

Name	Title
Stiles, Spencer S.	President
Menon, Viju	Vice President

Stryker Corporation
Howmedica Osteonics Corp Organizational Structure
April 30, 2025



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **HOWMEDICA OSTEONICS CORP.** as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/13/2003, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 06/24/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202506245836980
You may verify this certificate online at https://www.nvsilverflume.gov/home

UNITED STATES OF AMERICA

The State of Michigan

Department of Licensing and Regulatory Affairs

Lansing, Michigan

This is to certify:

Entity Name: STRYKER CORPORATION
Entity ID#: 800151233
Entity Type: Domestic Profit Corporation
Initial Filing Date: 02/20/1946
Delayed Effective Date:
Formation Jurisdiction: Michigan
Act Formed Under: 327-1931 Michigan General Corporation Act

That the above referenced entity was validly incorporated and said corporation is validly in existence under the laws of this state.

This certificate is issued in conformity with the Act it is formed under, to attest to the fact that the company is in good standing in Michigan as of this date and is duly authorized to transact business and for no other purpose.

This certificate is in due form, made by me as the proper officer, and is entitled to have full faith and credit given it in every court and office within the United States.

LICENSING AND REGULATORY AFFAIRS
Corporations, Securities & Commercial Licensing Bureau

In testimony whereof, I have hereunto set my hand, in the City of Lansing, on October 13, 2025.

Linda Clegg

Linda Clegg, Director
Corporations, Securities & Commercial Licensing Bureau

Certificate Number: 30877
Verify this certificate at: www.michigan.gov/corpverifycertificate

City of Reno

BUSINESS LICENSE

HOWMEDICA OSTEONICS CORP

DBA: STRYKER ORTHOPAEDICS

DAVID FURGASON

8745 TECHNOLOGY WAY UNIT B
RENO, NV 89521

LICENSE TYPE: GENERAL BUSINESS

LICENSE #: R153076A-LIC

EXPIRES: 12/31/2025

ANNUAL LICENSE

In accordance with the provisions of Reno Municipal Code Titles 4 and 5, the above named is hereby granted a City of Reno business license and is authorized to conduct the business activity listed. This license is valid until the expiration date unless suspended, revoked or cancelled and shall not be transferred or assigned.

DIRECTOR OF BUSINESS LICENSING

CITY CLERK

This license must be displayed in a conspicuous place pursuant to RMC Sec. 4.04.180(3). You may verify this business license online at www.onenv.us.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 10/17/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Aon Risk Services Central, Inc. MSC#17382 Aon PO Box 1447 Lincolnshire IL 60069 USA	**CONTACT NAME:** **PHONE (A/C. No. Ext):** (312) 381-1000 **FAX (A/C. No.):** **E-MAIL ADDRESS:**
INSURED Stryker Corporation & Subsidiaries 1941 Stryker Way Portage MI 49002 USA	**INSURER(S) AFFORDING COVERAGE** / **NAIC #** **INSURER A:** Old Republic Insurance Company 24147 **INSURER B:** **INSURER C:** **INSURER D:** **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** 570116277899 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			MWZY31876425	11/01/2025	11/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $500,000 Excluded $2,000,000 $3,000,000 $3,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY X PhysDamage-Self In			MWTB 318760-25	11/01/2025	11/01/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION						EACH OCCURRENCE AGGREGATE	
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		MWC31875925 AOS	11/01/2025	11/01/2026	X PER STATUTE OTH-ER	
A				MWXS31876125 Excess WC-MI SIR applies per policy terms & conditions	11/01/2025	11/01/2026	E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

FOR INFORMATIONAL PURPOSES ONLY

CERTIFICATE HOLDER

Stryker Corporation & Subsidiaries
1941 Stryker Way
Portage MI 49002 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier : EOCGL3MAL1MEL1M

Certificate No : 570116277899

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Howmedica Osteonics, Corp. MDEG License # (if applicable) _____

Physical Address 8745 Technology Way Unit B

City Reno State nv Zip 89521

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website www.stryker.com

Licensing Company Email jr.licensing@stryker.com

Section 2: Personal Information

First Dwight Middle Ryan Last Foreman

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 8745 Technology Way Unit B

City Reno State NV Zip 89521

Telephone [redacted] Email dwight.foreman@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Diamond Springs		08-90 8-94	
Address	City	State	Zip
	Diamond Springs	CA	95619
Diploma/Degree obtained, if any			
yes			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06-22 to current	[redacted]	Sparks	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06-14-06-21		Reno	NV	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Stryker			10-22 to current
Business Address	**City**	**State**	**Zip**
8745 Technology Way Unit B	Reno	NV	89521
Phone	**Title**	**Number of Employed Hours**	
916-747-1682	Surgical Case Coordinator	full time	
Description of Duties			
Coordinate day to day operations and logistics			

Business Name			From - To (MM/YY – MM/YY)
Stryker			01-17-9-22
Business Address	**City**	**State**	**Zip**
1150 Finacial Blvd	Reno	NV	89502
Phone	**Title**	**Number of Employed Hours**	
916-747-1682	Surgical Case Coordinator	full time	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11-11-25
Date

I, _____, **certify that as the MDEG Administrator for**

Howmedica Osteonics, Corp.

that I (initial that you have read and meet the following requirements):

1. df Have a high school diploma or its equivalent;
2. df Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. df Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. df Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DWIGHT FOREMAN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-11-25

Date

Board Use Only	Date Received: 11/12/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Stryker

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 8745 Technology Way Unit B

City Reno State NV Zip 89521

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 916-747-1682 Website _____

Licensing Company Email _____

Section 2: Personal Information

First Dwight Middle Ryan Last Foreman

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Sparks State NV Zip [redacted]

Telephone [redacted] Email dwight.foreman@stryker.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Diamond Springs			
Address	**City**	**State**	**Zip**
6205 Enterprise DR	Diamond Springs	ca	95619
Diploma/Degree obtained, if any			
yes			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6-221 to cmt	[redacted]	Sparks	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06-14-06-21		Reno	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Stryker			10-22 to Current	
Business Address		**City**	**State**	**Zip**
8745 Technology Way Unit B		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
916-747-1682	Surgical Case Coordinator		Full Time	
Description of Duties				
Coordinate surgery cases deliver medical implants				

Business Name			From - To (MM/YY – MM/YY)	
Stryker			1-17-9-22	
Business Address		**City**	**State**	**Zip**
1150 Financial Blvd		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
916-747-1682	Surgical Case Coordinator		Full Time	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Dwight Foreman, **certify that as the designated representative for**

Stryker,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. df I am at least 21 years of age;
3. df I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. df I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. df I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. df I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. df I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dwight Foreman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-16-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dwight Foreman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-16-25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Washoe

I, Dwight Foreman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8-28-25

Date

Subscribed and Sworn to before me this 28 day of August 2025

Notary Public Signature

Suzanne Derouen
Notary Public-State of Nevada
Appointment No. 25-3545-02
My Appointment Expires June 13, 2029

(Seal)

From: JR Licensing <jr.licensing@stryker.com>
Sent: Monday, December 1, 2025 2:02 PM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>; JR Licensing <jr.licensing@stryker.com>
Subject: Re: Nevada Out-of-State Wholesaler Application-Stryker Orthopaedics

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.
Hi Maria,

Attached you will find the updated COI

Below are employee names:

8745 Technology Way, Reno, NV 89502

1. Dwight Foreman
2. Ryan Mcdonald

5905 South Decatur Blvd., Las Vegas, NV 89118

1. William Wakefield
2. Errol Sapp
3. Kenneth Kammerer
4. Carlos Verde
5. Ryan McCullough
6. Butterscotch Tate
7. Butterscotch Tate II
8. Duke Becker
9. Louie Salenga

Please let me know if anything else is needed.

Jenn Santos (She/Her)
Sr. Project Associate
Stryker
Field Functional Commercial Operations
Stryker.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-13149

stryker

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan			38-1239739
(State of incorporation)			(I.R.S. Employer Identification No.)
1941 Stryker Way,	Portage,	Michigan	49002
(Address of principal executive offices)			(Zip Code)

(269) 385-2600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.10 Par Value	SYK	New York Stock Exchange
2.125% Notes due 2027	SYK27	New York Stock Exchange
3.375% Notes due 2028	SYK28	New York Stock Exchange
0.750% Notes due 2029	SYK29	New York Stock Exchange
2.625% Notes due 2030	SYK30	New York Stock Exchange
1.000% Notes due 2031	SYK31	New York Stock Exchange
3.375% Notes due 2032	SYK32	New York Stock Exchange
3.625% Notes due 2036	SYK36	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging growth company	☐
Non-accelerated filer	☐	Small reporting company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $123,147,898,554 at June 30, 2024. There were 381,579,123 shares outstanding of the registrant's common stock, $0.10 par value, on January 31, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement to be filed with the U.S. Securities and Exchange Commission relating to the 2025 Annual Meeting of Shareholders (the 2025 proxy statement) are incorporated by reference into Part III.

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PART I

ITEM 1. BUSINESS.

Stryker Corporation (Stryker or the Company) is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually.

Our core values guide our behaviors and actions and are fundamental to how we execute our mission.

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity	Accountability	People	Performance
We do what's right.	We do what we say.	We grow talent.	We deliver.

Stryker was incorporated in Michigan in 1946 as the successor company to a business founded in 1941 by Dr. Homer H. Stryker, a prominent orthopaedic surgeon and inventor of several medical products. Our products are sold in approximately 75 countries through company-owned subsidiaries and branches as well as third-party dealers and distributors, and include surgical equipment and surgical navigation systems; endoscopic and communications systems; patient handling, emergency medical equipment and intensive care disposable products; clinical communication and artificial intelligence-assisted virtual care platform technology; neurosurgical and neurovascular devices; implants used in joint replacement and trauma surgeries; Mako Robotic-Arm Assisted technology; spinal devices; as well as other products used in a variety of medical specialties. Most of our products are marketed directly to doctors, hospitals and other healthcare facilities.

As used herein, and except where the context otherwise requires, "Stryker," "we," "us," and "our" refer to Stryker Corporation and its consolidated subsidiaries.

Business Segments and Geographic Information

We segregate our operations into two reportable business segments: (i) MedSurg and Neurotechnology and (ii) Orthopaedics. Financial information regarding our reportable business segments and certain geographic information is included under "Consolidated Results of Operations" in Item 7 of this report and Note 14 to our Consolidated Financial Statements.

In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics and Spine, the Interventional Spine (IVS) portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. In addition, we changed the name of our "Orthopaedics and Spine" operating segment to "Orthopaedics."

Quarterly Net Sales - Enabling Technologies

	2024	2023	2022
Mar 31	$ 30	$ 31	$ 30
Jun 30	$ 31	$ 32	$ 25
Sep 30	$ 59	$ 54	$ 44
Dec 31	$ 32	$ 32	$ 32
Total	$ 152	$ 149	$ 131

Quarterly Net Sales - IVS

	2024	2023	2022
Mar 31	$ 98	$ 77	$ 65
Jun 30	$ 98	$ 83	$ 73
Sep 30	$ 117	$ 84	$ 72
Dec 31	$ 100	$ 83	$ 72
Total	$ 413	$ 327	$ 282

Quarterly Net Sales - Spinal Implants

	2024	2023	2022
Mar 31	$ 171	$ 176	$ 183
Jun 30	$ 178	$ 181	$ 193
Sep 30	$ 186	$ 180	$ 182
Dec 31	$ 172	$ 176	$ 175
Total	$ 707	$ 713	$ 733

Net Sales by Reportable Segment

	2024		2023		2022	
MedSurg and Neurotechnology	$ 13,518	60 %	$ 12,163	59 %	$ 10,893	59 %
Orthopaedics	9,077	40	8,335	41	7,556	41
Total	$ 22,595	100 %	$ 20,498	100 %	$ 18,449	100 %

MedSurg and Neurotechnology

MedSurg products include surgical equipment, patient and caregiver safety technologies, and navigation systems (Instruments), endoscopic and communications systems (Endoscopy), and patient handling, emergency medical equipment, intensive care disposable products and clinical communication and artificial intelligence-assisted virtual care platform technology (Medical). Neurotechnology includes neurosurgical, neurovascular and craniomaxillofacial implant products. Our neurotechnology offering includes products used for minimally invasive endovascular procedures; a comprehensive line of products for traditional brain and open skull based surgical procedures; orthobiologic and biosurgery products, including synthetic bone grafts and vertebral augmentation products (Neuro Cranial); and minimally invasive products for the treatment of acute ischemic and hemorrhagic stroke (Neurovascular). The craniomaxillofacial implant offering includes cranial, maxillofacial and chest wall devices as well as dural substitutes and sealants.

We are one of five leading global competitors in Instruments; the other four being Zimmer Biomet Holdings, Inc. (Zimmer), Medtronic plc (Medtronic), Johnson & Johnson MedTech (a subsidiary of Johnson & Johnson) and ConMed Linvatec, Inc. (a subsidiary of CONMED Corporation). We are one of seven leading global competitors in Endoscopy; the other six being Karl Storz GmbH & Co., Olympus Optical Co. Ltd., Smith & Nephew plc (Smith & Nephew), ConMed Linvatec, Arthrex, Inc. and STERIS plc. We are one of five leading global competitors in Medical; the other four being Baxter International Inc., Zoll Medical Corporation, Medline Industries and Ferno-Washington, Inc. We are one of five leading global competitors in Neurotechnology; the other four being Medtronic, Johnson & Johnson Medtech, Terumo Corporation and Penumbra, Inc.

Composition of MedSurg and Neurotechnology Net Sales

	2024		2023		2022	
Instruments	$ 2,834	21 %	$ 2,534	21 %	$ 2,245	21 %
Endoscopy	3,389	25	3,068	25	2,759	25
Medical	3,852	28	3,459	28	3,031	28
Neurovascular	1,307	10	1,226	11	1,200	11
Neuro Cranial	2,136	16	1,876	15	1,658	15
Total	$ 13,518	100 %	$ 12,163	100 %	$ 10,893	100 %

In 2024 Instruments launched SurgiCount+ powered by Triton, which combines our existing sponge counting technology with artificial intelligence and quantifying blood loss software. We also launched CoPilot, which combines with our Spine Q guidance system to help surgeons plan and perform certain spinal procedures, including supporting bone resection, pedicle preparation and screw delivery.

In addition we completed the acquisition of Vertos Medical, Inc., a leader in interventional pain management solutions for chronic lower back pain caused by lumbar spinal stenosis. The acquisition of Vertos is complementary to our Interventional Spine business as we continue to focus on advanced pain procedures.

Endoscopy continued to deliver its 4K 1788 Camera platform to the market. Our 1788 Camera platform features several enhancements for a broader range of clinical applications and specialties, including urology, neurology and ear, nose and throat and can be used to visualize indocyanine green and Cytalux.

Medical launched the LIFEPAK 35 monitor/defibrillator, our next generation platform designed to optimize care with new clinical features such as the new Glasgow 30.4 algorithm, cprINSIGHT, 15-lead monitoring capabilities, and STJ insight and mapping. LIFEPAK 35 combines a modern intuitive touch screen display and increased processing power with Bluetooth and WiFi data connectivity.

Medical also completed the acquisition of care.ai, a virtual care and ambient intelligence solutions platform. care.ai adds complementary technology that is expected to integrate seamlessly with the Vocera platform (Vocera) and Stryker's devices, providing customers with an enterprise-wide ecosystem that is intended to deliver dynamic clinical workflows and further the development of smart care facilities.

Neurovascular initiated a targeted launch of the Surpass Elite Flow Diverting Stent (FDS) in the U.S. and South Korea. Surpass Elite FDS is designed to reduce thrombin generation when compared to unmodified stents. Additionally, Neurovascular launched Surpass Evolve FDS in Japan. The Stryker FDS platform is designed to effectively treat aneurysms by redirecting blood flow away from the aneurysm to promote healing.

Orthopaedics

Orthopaedics products primarily include implants used in total joint replacements, such as hip, knee and shoulder, and trauma and extremities surgeries. We bring patients and physicians advanced implant designs and specialized instrumentation that make orthopaedic surgery and recovery simpler, faster and more effective. We support surgeons with the technologies, products and services they need to support each patient's clinical challenge.

We are one of four leading global competitors for joint replacement and trauma and extremities products and robotics; the other three being Zimmer, Johnson & Johnson MedTech and Smith & Nephew.

Composition of Orthopaedics Net Sales

	2024		2023		2022	
Knees	$ 2,447	27 %	$ 2,273	27 %	$ 1,997	26 %
Hips	1,704	19	1,544	18	1,413	19
Trauma and Extremities	3,507	39	3,147	38	2,807	37
Spinal Implants	707	8	713	9	733	10
Other	712	8	658	8	606	8
Total	$ 9,077	100 %	$ 8,335	100 %	$ 7,556	100 %

In 2024 we continued the full commercial launch of our Triathlon Hinge revision knee system. Triathlon Hinge received approval in August of 2023 and is now released in the U.S., Canada and New Zealand. We also continued delivering growth in total hip arthroplasty, particularly in the primary segment where Direct Anterior Reconstructive Technology and Mako Total Hip can help to reduce, if not eliminate, a surgeon's use of intraoperative fluoroscopy during direct anterior hip procedures. With the acquisition of SERF SAS, we strengthened distribution in key European markets and continue to scale differentiated solutions such as the Novae monolithic dual mobility cup engineered to deliver greater hip stability and reduce dislocation risk.

We continued to expand our global footprint of Mako SmartRobotics™ in 2024 which is now sold in more than 45 countries. To date more than one million robotic Mako Total Knees and 1.5 million robotic procedures across Total Hips, Total Knees and Partial Knees have been performed globally. Stryker's Joint Replacement division also launched the "Scan. Plan. Mako Can." direct to patient campaign, accelerating awareness of Mako technology in the U.S.

Our spine enabling technologies portfolio includes best in class imaging solutions, image-guided surgical technology, patient specific implants and digital health solutions supporting surgeons and their patients throughout the continuum of care.

In December 2024 we performed our first Mako Shoulder procedure using robotic-arm assistance to remove bone, prepare the glenoid surface and enable positioning and placement of the Perform Reversed Glenoid implant.

In 2024 Trauma launched Pangea, a comprehensive variable angle plating portfolio designed to optimize plate fit to bone utilizing simple, intuitive instrumentation that enhances ease of use and reproducibility. These combined solutions empower Stryker to deliver a complete portfolio across all trauma segments.

Raw Materials and Inventory

Raw materials essential to our business are generally readily available from multiple sources; however, certain of our raw materials are currently sourced from single suppliers. Substantially all products we manufacture are stocked in inventory, while certain MedSurg products are assembled to order.

Patents and Trademarks

Patents and trademarks are significant to our business to the extent that a product or an attribute of a product represents a unique design or process. Patent protection of such products restricts competitors from duplicating these unique designs and features. We seek to obtain patent protection on our products whenever appropriate for protecting our competitive advantage. On December 31, 2024 we owned approximately 5,600 United States patents and approximately 8,600 patents in other countries.

Seasonality

Our business is generally not seasonal in nature; however, the number of orthopaedic implant surgeries is typically lower in the

summer months, and sales of capital equipment are generally higher in the fourth quarter.

Competition

In each of our product lines we compete with local and global companies. The development of innovative products is important to our success in all areas of our business. Competition in research involving the development and improvement of new and existing products and processes is particularly significant. The competitive environment requires substantial investments in continuing research and maintaining sales forces.

We believe our commitment to innovation, quality and service and our reputation differentiates us in the highly competitive product categories in which we operate and enables us to compete effectively. We believe that our competitive position in the future will depend to a large degree on our ability to develop new products and make improvements to existing products.

Regulation

Our businesses are subject to varying degrees of governmental regulation in the countries in which we operate, and the general trend is toward increasingly stringent regulation. We are required to comply with the unique regulatory requirements of each country in which we market and sell our products.

In the United States the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act and its subsequent amendments and the regulations issued and proposed thereunder provide for federal regulation by the United States Food and Drug Administration (FDA) of the design, manufacture and marketing of medical devices, including most of our products. In addition, state licensing requirements often apply to certain of our business operations and products. On the federal level, many of our new products fall into FDA classifications that require notification submitted as a 510(k) and review by the FDA before we begin marketing them. Certain of our products require extensive clinical testing, consisting of safety and efficacy studies, followed by pre-market approval applications for specific surgical indications. Certain of our products also fall under other FDA classifications, such as drugs and Human Cells, Tissues, and Cellular and Tissue-Based Products.

The FDA's Quality System regulations set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

The European Union enacted the European Union Medical Device Regulation in May 2017 with an original effective date of May 2022, which imposes stricter requirements for the marketing and sale of medical devices, including in the areas of clinical evaluation requirements, quality systems, labeling and post-market surveillance. Extended transition timelines were published in 2023 which range from May 2026 through December 2028 depending on the type of device and our implementation is on track to meet these timelines.

Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. It is not possible to predict at this time the long-term impact of such cost containment measures on our future business. In addition, business practices in the healthcare industry are scrutinized, particularly in the United States, by federal and state government agencies. Any resulting investigations and prosecutions potentially carry the risk of significant civil and criminal penalties.

Environment

We are subject to various rules and regulation in the United States and internationally related to the protection of human health and the environment. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe our policies, practices and procedures are properly designed to comply, in all material respects, with applicable environmental laws and regulations. We do not expect compliance with these requirements to have a material effect on purchases of property, plant and equipment, cash flows, net earnings or competitive position.

Employees

On December 31, 2024 we had approximately 53,000 employees globally, with approximately 27,000 employees in the United States. Our talented employees are an integral reason for our standing as a global leader in medical technologies where, together with our customers, we are driven to make healthcare better. Our company values of integrity, accountability, people and performance are a key component of that mission. Our people, as one of our core values, continue to be a key focus.

Our success depends on our ability to attract the best talent. To do so, we continue to focus on creating and maintaining a great workplace. We believe in attracting the right people, maintaining and building employee engagement and developing our employees. We believe when people are able to do what they do best, they will look forward to coming to work and, in turn, will deliver great business results.

Our leadership team and Board of Directors receive regular updates on our people and culture strategy and provide feedback on our strategy and goals, including alignment to our mission and values, peer benchmarking and stakeholder feedback.

Employee Development

Our employee development is extensive and exists at all levels of the organization, including company-wide training on our Code of Conduct, job-related technical training and management and leadership training. Our development programs include on-the-job learning, coaching and mentoring, management and leadership development courses, team building and collaboration training and immersive experiences with expert partners.

We encourage all employees to establish development objectives, in partnership with their manager, to help employees gain the needed development experience to grow their careers.

Employee Engagement

An engaged workplace culture that drives performance and business outcomes is central to our mission. Listening to and learning from our employees forms the foundation of an engaging culture. More than 90% of our employees participate in our annual engagement survey, which provides a valued platform for listening and allows us to take action based on the feedback collected.

We supplement our annual engagement survey with targeted pulse surveys to gather feedback on topics relevant to the current climate.

We also provide tools and resources that enable managers and teams to act on the insights we gain from our surveys and to drive employee engagement and strong business outcomes.

Diversity, Equity and Inclusion (DE&I)

An essential part of our culture is respecting each individual's strengths and values. Building on this foundation, we are focused on maintaining an inclusive, engaging work environment in keeping with our values of integrity and people. Our DE&I strategy is centered around these three commitments:

- Strengthen the diversity of our workforce
- Advance a culture of inclusion, engagement and belonging
- Maximize the power of inclusion to drive innovation and growth

We are advancing our commitments through the following actions, among others:

- Increasing access to talent through strategic partnerships and campaigns
- Growing and engaging talent with a range of opportunities to learn and develop
- Aligning our employee resource groups, which are open to all employees, to focus on creating community and belonging

Attracting and Hiring

We understand that every employee drives our success. We focus on attracting, identifying and selecting strong candidates who will be successful at Stryker and ensuring that each person we hire brings the talent, expertise and passion we need to continue to be successful.

Health and Safety

Ensuring our employees' safety is a top priority. It is a responsibility that we share throughout the company and one that has evolved to meet the needs of our workforce. Employees' safety risks vary depending on the roles they perform, so we tailor our safety efforts accordingly.

Competitive Pay and Benefits

Our compensation and benefits programs are designed to attract and retain top talent and to incentivize performance and alignment to our mission and values.

We offer market-competitive base pay and benefits to our employees in countries around the world. We regularly evaluate our compensation and benefit offerings and levels, using recognized outside consulting firms to ensure internal fairness and competitiveness in our offerings.

Most of our employees also have variable components to their compensation packages that reward employees based on individual, business unit and/or company-wide performance.

Our proxy statement provides more detail on the competitive compensation programs we offer to our executive officers.

Information about our Executive Officers

As of January 31, 2025

Name	Age	Title	First Became an Executive Officer
Kevin A. Lobo	59	Chair, Chief Executive Officer and President	2011
Yin C. Becker	61	Vice President, Chief Corporate Affairs Officer	2016
William E. Berry Jr.	59	Vice President, Chief Accounting Officer	2014
Glenn S. Boehnlein	63	Vice President, Chief Financial Officer	2016
M. Kathryn Fink	55	Vice President, Chief Human Resources Officer	2016
Robert S. Fletcher	54	Vice President, Chief Legal Officer	2019
Viju S. Menon	57	Group President, Global Quality and Operations	2018
J. Andrew Pierce	51	Group President, MedSurg and Neurotechnology	2021
Spencer S. Stiles	48	Group President, Orthopaedics	2021

Each of our executive officers was elected by our Board of Directors to serve in the office indicated until the first meeting of the Board of Directors following the annual meeting of shareholders in 2025 or until a successor is chosen and qualified or until his or her resignation or removal. Each of our executive officers held the position above or served Stryker in various executive or administrative capacities for at least five years.

Available Information

Our main corporate website address is *www.stryker.com*. The information on our website is not incorporated by reference into this report. Copies of our filings with the United States Securities and Exchange Commission (SEC) are available free of charge on our website within the "Investors Relations" section as soon as reasonably practicable after having been electronically filed or furnished to the SEC. All SEC filings are also available at the SEC's website at *www.sec.gov*.

ITEM 1A. RISK FACTORS.

This report contains statements that are not historical facts and are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current projections about operations, industry conditions, financial condition and liquidity. Words that identify forward-looking statements include, without limitation, words such as "may," "could," "will," "should," "possible," "plan," "predict," "forecast," "potential," "anticipate," "estimate," "expect," "project," "intend," "believe," "may impact," "on track," "goal," "strategy" and words and terms of similar substance used in connection with any discussion of future operating or financial performance, an acquisition or our businesses. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Those statements are not guarantees and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially and adversely from these forward-looking statements, historical experience or our present expectations. Some important factors that could cause our actual results to differ from our expectations in any forward-looking statements include:

- weakening of economic conditions, or the anticipation thereof, that could adversely affect the level of demand for our or Inari Medical, Inc.'s ("Inari") products;
- geopolitical risks, including from international conflicts, which could, among other things, lead to increased market volatility;

- pricing pressures generally, including cost-containment measures that have adversely affected and could in the future adversely affect the price of or demand for our or Inari's products;
- changes in foreign currency exchange markets;
- legislative and regulatory actions;
- unanticipated issues arising in connection with clinical studies and otherwise that affect approval of new products, including Inari products, by the FDA and foreign regulatory agencies;
- inflationary pressures;
- increased interest rates or interest rate volatility;
- supply chain disruptions;
- changes in labor markets;
- changes in coverage and reimbursement levels from third-party payors;
- changes in the competitive environment;
- breaches, failures or other disruptions of our or our vendors' or customers' information technology systems or products, including by cyber-attack, data leakage, unauthorized access or theft;
- a significant increase in product liability claims;
- the ultimate total cost with respect to recall-related and other regulatory and quality matters;
- the impact of investigative and legal proceedings and compliance risks;
- resolution of tax audits;
- changes in tax laws and regulations;
- the impact of legislation to reform the healthcare system in the United States or other countries;
- costs to comply with medical device regulations;
- changes in financial markets;
- changes in our credit ratings;
- our ability to integrate and realize the anticipated benefits of acquisitions in full or at all or within the expected timeframes, including our acquisition of Inari;
- our ability to realize any anticipated cost savings;
- potential negative impacts resulting from climate change or other environmental, social and governance and sustainability related matters;
- the impact on our operations and financial results of any public health emergency and any related policies and actions by governments or other third parties;
- uncertainties as to the timing of the tender offer for shares of Inari common stock and the subsequent merger with Inari;
- uncertainties as to how many of Inari's stockholders will tender their shares in the tender offer;
- the failure to satisfy any of the closing conditions to the acquisition of Inari, including the expiration or termination of the Hart-Scott-Rodino Antitrust Improvements Act waiting period (and the risk that such governmental approval may result in the imposition of conditions that could adversely affect the expected benefits of the transaction);
- delays in consummating the acquisition of Inari or the risk that the transaction may not close at all;
- unexpected liabilities, costs, charges or expenses in connection with the acquisition of Inari;
- the effects of the proposed Inari transaction (or the announcement thereof) on the parties' relationships with employees, customers, other business partners or governmental entities; and
- other risks detailed in our filings with the SEC.

While we believe that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement. We expressly disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that affect the likelihood that actual results will differ from those contained in the forward-looking statements.

Our operations and financial results are subject to various risks and uncertainties discussed below that could materially and adversely affect our business, cash flows, financial condition and results of operations. Additional risks and uncertainties not currently known to us or that we currently deem not to be material or that could apply to any company may also materially and adversely affect our business, cash flows, financial condition or results of operations. If any of the risks discussed below or other risks actually occur or continue to occur, our business, financial condition, operating results or cash flows could be materially adversely affected. Accordingly, you should carefully consider the following risk factors, as well as other information contained in or incorporated by reference in this report.

BUSINESS AND OPERATIONAL RISKS

We use a variety of raw materials, components, devices and third-party services in our global supply chains, production and distribution processes; significant shortages, price increases or unavailability of third-party services have in the past increased, and could in the future increase, our operating costs and could require significant capital expenditures or adversely impact the competitive position of our products: Our reliance on certain suppliers to secure raw materials, components and finished devices, and on certain third-party service providers, such as sterilization service providers, exposes us to the risk of product shortages and unanticipated increases in prices, whether due to inflationary pressure, regulatory changes, litigation exposure, geopolitical tensions or otherwise. For example, in the past we experienced limited product availability due to an electronic components shortage in certain product lines. If a similar shortage occurs in the future with respect to any raw materials or components, we may not be able to obtain them from our suppliers on a timely basis, or at all, or identify alternative suppliers. In addition, several raw materials, components, finished devices and services are procured from a sole source due to, among other things, the quality considerations, unique intellectual property considerations or constraints associated with regulatory requirements. If sole-source suppliers or service providers are unable or unwilling to deliver these materials or services as a result of financial difficulties, business disruptions, acquisition by a third party, natural disasters or otherwise, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer, possibly materially. In certain cases, we may not be able to establish additional or replacement suppliers for such materials or service providers for such services in a timely or cost-effective manner, often as a result of FDA and other regulations that require, among other things, validation of materials, components and services prior to their use in or with our products. In certain instances we have been unable to meet demand due to supply chain challenges, which has led to loss of sales. Although the impacts have not been material to date, an inability to meet demand due to supply chain challenges in the future could materially adversely impact our reputation, the competitive position of our products and our business. Any of the foregoing risks could have a material adverse impact on our profitability and results of operations.

In addition, in recent years, the market has experienced inflationary pressures in part due to global supply chain disruptions, labor shortages and other impacts following the COVID-19 pandemic. Inflation in the United States and in many of the countries where we conduct business has resulted in, and may in the future result in, high interest rates and increased capital, energy, shipping and labor costs, weakening or strengthening exchange rates against the United States Dollar and other similar effects. We have experienced, and may in the future experience, inflationary increases in manufacturing costs and operating expenses, as well as negative impacts from weakening or strengthening exchange rates against the United States Dollar. Although we have been able to pass certain cost increases on to our customers, we have not been able to pass along all cost increases and we cannot guarantee that we will be able to do so in the future. Inflation, high interest rates or interest rate volatility may also cause our customers to reduce or delay orders for our products and services. Any of the foregoing could have a material adverse impact on our sales, profitability and results of operations.

We are subject to pricing pressures as a result of cost containment measures in the United States and other countries and other factors, including changes in reimbursement practices and coverage policies and third-party payor cost containment measures: Initiatives to limit the growth of general healthcare expenses and hospital costs are ongoing in the markets in which we do business. These initiatives are sponsored by government agencies, legislative bodies and the private sector and include price regulation and competitive pricing. For example, China has implemented a volume-based procurement process designed to decrease prices for medical devices and other products. Pricing pressure has also increased due to continued consolidation among healthcare providers, trends toward managed care, the shift toward governments becoming the primary payers of healthcare expenses, reduction in coverage or reimbursement levels and medical procedure volumes and government laws and regulations relating to sales and promotion, reimbursement and pricing generally. Coverage policies and reimbursement levels can vary across the payer community globally, regionally, and locally, and may affect which products customers purchase, the market acceptance rate for new technologies and the prices customers are willing to pay for those products in a particular jurisdiction. Furthermore, any changes to the coverage or reimbursement landscape, or adverse decisions relating to our products by administrators of these systems could significantly reduce reimbursement for procedures using our products or result in denial of reimbursement for those products, which could adversely affect customer demand, or the price customers are willing to pay for such products. Public and private payers have challenged, and are expected to continue to challenge, prices charged for medical products and services. Such downward pricing pressures from any or all of these payers may result in an adverse effect on our business, results of operations, financial condition and cash flows. We have also reduced prices for certain products due to increased competition and if we further reduce prices, we could become less profitable. In addition, due to healthcare industry consolidation in recent years, competition to provide goods and services to industry participants has become, and may continue to become, more intense, and this consolidation has produced, and may continue to produce, larger enterprises with more bargaining power. Pricing pressures related to any of the foregoing or other factors have impacted and could in the future impact our results of operations and profitability.

We operate in a highly competitive industry in which competition and the regulatory burden in the development and improvement of new and existing products is significant: The markets in which we compete are highly competitive, and a significant element of our strategy is to increase revenue growth by focusing on innovation, new product development and improvement of existing products. New business models, products and surgical procedures, as well as improvements to existing products, are introduced on an ongoing basis and our present or future products could be rendered obsolete or uneconomical by internal or external technological advances, including by our existing competitors and new market entrants, which could adversely impact demand for certain of our existing products. The success of our products and services depends on, among other things, our ability to properly identify customer needs and predict future needs; innovate and develop new technologies, services and applications at an accelerated pace; and appropriately allocate our research and development spending to products and services with higher growth. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging technologies such as robotics, artificial intelligence and machine learning in their product offerings, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing and other resources or be more successful in attracting potential customers, employees and strategic partners. There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products, our ability to maintain or expand our market position in the markets in which we participate may be negatively impacted.

We may be unable to maintain adequate working relationships with healthcare professionals: We work with healthcare professionals in a transparent and responsible manner and seek to maintain these relationships with respected physicians and medical personnel in healthcare organizations, such as hospitals and universities, who assist in product research and development. We rely on these professionals to assist us in the development and improvement of proprietary products. If we are unable to maintain these relationships due to regulatory restrictions, hospital access restrictions for non-patients or for other reasons, our ability to develop, market and sell new and improved products could be adversely affected.

We rely on indirect distribution channels and major distributors that are independent of Stryker: In many markets we rely on indirect distribution channels to market, distribute and sell our products. These indirect channels often are the main point of contact for the healthcare professionals and healthcare organization customers who buy and use our products. Our ability to continue to market, distribute and sell our products may be at risk if the indirect channels become insolvent, choose to sell competitive products, choose to stop selling medical technology, fail to adhere to Stryker requirements or are subject to new or additional government regulation.

We are subject to risks associated with our extensive global operations: We develop, manufacture and distribute our products globally. Our global operations are subject to risks and costs related to, among other things, changes in coverage or reimbursement levels from third-party payors in the United States and other countries; changes in regulatory requirements (such as the staggered phase-in period for manufacturers to comply with

the European Union Medical Device Regulation (MDR) through December 2028); differing local product preferences and product requirements; diminished protection of intellectual property in some countries; tariffs and other trade protection measures, as well as increasing localization and protectionism policies in certain jurisdictions; international trade disputes and import or export requirements; difficulty in staffing and managing foreign operations; introduction of new internal business structures and programs; political and economic instability and uncertainty; current or potential geopolitical conflicts, such as the tensions between China and Taiwan and the wars in Ukraine and the Middle East, and related sanctions and other developments; disruptions of transportation, including port closures, increased border controls or border closures or reduced transportation availability, due to military conflicts, a global pandemic of contagious diseases like COVID-19 or otherwise; increased energy or transportation costs; fluctuations in currency exchange rates and financial markets; and increased security threats to our supply chain. Many of these risks are rapidly evolving and subject to an accelerating pace of change. Our business could be adversely impacted if we are unable to successfully manage these and other risks of global operations in an increasingly volatile environment. In addition, in many countries, the laws and regulations applicable to us or our industry are evolving, and we have in certain cases become subject to divergent and conflicting laws and regulations across our operations, which has increased the risks we are subject to.

We may be unable to capitalize on previous or future acquisitions: In addition to internally developed products, we invest in new products and technologies through acquisitions. Such investments are inherently risky, and we cannot guarantee that any acquisition will be successful or will not have a material unfavorable impact on us. The risks include the activities required and resources allocated to integrate new businesses, diversion of management time that could adversely affect management's ability to focus on other projects, the inability to realize the expected benefits, savings or synergies from the acquisition, the loss of key personnel, litigation resulting from the acquisition and exposure to unexpected liabilities of acquired companies. Certain acquisitions are subject to antitrust and competition laws, and antitrust scrutiny by regulatory agencies and changes to the regulatory approval process in the United States and foreign jurisdictions may cause approvals to take longer than anticipated to obtain, not be obtained at all, or contain burdensome conditions, which may jeopardize, delay or reduce the anticipated benefits of acquisitions to us and could impede the execution of our business strategy. In addition, we cannot be certain that the businesses we acquire will become or remain profitable.

We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site: We rely extensively on information technology (IT) systems to conduct business. In addition, we rely on networks and services, including internet sites, cloud and software-as-a-service solutions, data hosting and processing facilities and tools and other hardware, software (including open-source software) and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. Furthermore, numerous and evolving cybersecurity threats have posed, and will continue to pose, risks to the security of our IT systems, networks and product offerings, as well as the confidentiality, availability and integrity of our data. Emerging technologies such as generative artificial intelligence (AI) may be used by malicious actors to create more targeted phishing narratives, spread disinformation about us or our products or otherwise strengthen social engineering capabilities. Some of our products, services, and information technology systems contain or use open-source software which poses particular risks, including potential security vulnerabilities, licensing compliance issues and quality issues. We, our customers and third-party hosting services have experienced, and expect to continue to experience, security breaches of, unauthorized access to, and disruptions of, products or systems. While such breaches, unauthorized access and disruptions have not had a material effect on us to date, we cannot guarantee that any future breach or unauthorized access will not be material and any breach or unauthorized access could impact the use of such products and systems and the security of information stored therein. Although we have made investments and expect to continue to make investments seeking to address these threats, including monitoring of networks and systems, use of artificial intelligence, hiring of experts, employee training and security policies for employees and third-party providers, the techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures.

When cybersecurity or other technology related incidents occur, we follow our incident response protocols and address them in accordance with applicable governmental regulations and other legal requirements. Our response to these incidents and our investments to protect our product offerings and information technology infrastructure and data may not shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Moreover, given the increasing complexity and sophistication of the techniques used by threat actors to obtain unauthorized access or disable or degrade systems, a cyberattack could occur and persist for an extended period of time before being detected, and we may not anticipate these acts or mitigate them adequately or timely, which may compound damages before the incident is discovered or remediated. The extent of a particular cyber incident and the steps that we may need to take to investigate the incident may not be immediately clear, and it may take a significant amount of time before such investigation can be completed and full and reliable information about the incident is known. New regulations may require us to disclose information about a material cybersecurity incident before it has been resolved or fully investigated. Additionally, as threats continue to evolve and increase, and as the regulatory environment and customer requirements related to information security, data collection and use, and privacy become increasingly rigorous, we may be required to devote significant additional resources to modify and enhance our security controls and to identify and remediate any security vulnerabilities, which could adversely impact our net income. In addition, a significant number of our employees working remotely has exposed us, and may continue to expose us, to greater risks related to cybersecurity and cyber-liability.

Hardware and software failures or delays in our key information technology systems, networks, processes or sites could disrupt our operations, cause the loss of confidential information or otherwise adversely impact our business. Our systems, networks, processes and sites may be vulnerable to damage, disruptions and shutdown from a variety of sources, including malfunctions in maintenance updates or security patches, design defects, the age of the technology, network failures, modernization or other initiatives, human acts and natural disasters. For example, some of our information technology systems contain legacy third-party software components for which we depend on a layered security

approach to protect against exploitation, which may not be effective. Any such damage or disruptions could also compromise the security of our information systems and networks. These issues can also arise as a result of failures by, or in the software or hardware of, third parties, including networks or service providers, with whom we do business and over whom we have limited or no control. Any disruption or failure of our systems, networks, processes or sites could have a material impact on our business and operations.

If our IT systems, networks or processes are damaged or cease to function properly for any reason, the networks, service providers, hardware or software we rely upon fail to function properly, or we or one of our third-party providers suffer a loss or disclosure of our business or stakeholder information due to any number of causes ranging from catastrophic events or power outages to improper data handling or security breaches or unauthorized access and our business continuity plans do not effectively address these failures on a timely basis, we may be exposed to reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

An inability to successfully manage the implementation of our new commercial global enterprise resource planning (ERP) system could adversely affect our operations and operating results: We are in the process of implementing a new commercial ERP system. This system will replace many of our existing operating and financial systems. The implementation is a major undertaking, both financially and from a management and personnel perspective. Any material disruptions, delays or deficiencies in the design and implementation of our new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business.

We may be unable to attract, develop and retain executives and key employees: Our sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. Our future performance also depends in large part on the continued services of our senior management. If we are unable to recruit, hire, develop and retain a talented, competitive workforce in our highly competitive industry, or if we are unable to plan effective succession for the future, we may not be able to meet our strategic business objectives. Inflationary pressures, labor demand and shortages and other macroeconomic factors have increased and could further increase the cost of labor and could harm our ability to recruit, hire and retain talented employees. In addition, increased unionization could negatively impact our labor costs and ability to create an engaging, connected culture, which could adversely affect our ability to recruit, hire, develop and retain a talented, competitive workforce. Further, if we are unable to maintain competitive and equitable compensation and benefit programs, including incentive programs which reward financial and operational performance, our ability to recruit, hire, engage, motivate and retain talent could be negatively affected. Additionally, if we are unable to maintain an inclusive culture that aligns our diverse workforce with our mission and values, it could adversely impact our ability to recruit, hire, develop and retain key talent. Further, our remote and hybrid work practices, ability to provide flexible and alternative work arrangements, and our practices relating to corporate responsibility may not meet the needs or expectations of our employees, including senior management or other key employees, which could negatively impact our ability to attract and retain highly skilled employees, or may harm our culture and/or decrease employee engagement, which could adversely impact our ability to recruit, hire, develop and retain a talented, competitive workforce.

Effective succession planning is also important to our long-term success. Failure to ensure effective transfer of knowledge and smooth transitions involving executives and other key employees could hinder our strategic planning and execution. Changes in our management team may be disruptive to our business, and any failure to successfully integrate key new hires or promoted employees could adversely affect our business and results of operations. The loss of the services of any of our senior management or other key personnel, or our inability to attract highly qualified senior management and other key personnel, could harm our business. Our ability to execute our business strategy could be impaired if we are unable to replace such persons timely. In addition, recent legal and regulatory changes affect our ability to enforce post-termination obligations from certain employees with respect to non-competition, non-solicitation and protection of confidential information. This may negatively impact our ability to retain employees and protect our information and relationships with customers and other third parties.

Interruption of manufacturing operations could adversely affect our business: We and our suppliers have manufacturing and supply sites all over the world. However, the manufacturing of certain of our product lines is concentrated in one or more plants or geographic regions. We have principal manufacturing and distribution facilities in the United States in Arizona, California, Florida, Illinois, Indiana, Michigan, Minnesota, New Jersey, Puerto Rico, Tennessee, Texas, Utah, Virginia and Washington, and outside the United States in China, France, Germany, Ireland, Mexico, the Netherlands, Poland, Switzerland and Turkey. Damage to our facilities, to our suppliers' or service providers' facilities, or to our central distribution centers as a result of natural disasters, fires, explosions or otherwise, as well as issues in our manufacturing arising from a failure to follow specific internal protocols and procedures, compliance concerns relating to the quality systems regulation, equipment breakdown or malfunction, IT system failures or cybersecurity incidents, environmental hazard incidents or changes to environmental regulations or other factors, could adversely affect the availability of our products. In the event of an interruption in manufacturing, we may be unable to move quickly to alternate means of producing and distributing affected products to meet customer demand. In the event of a significant interruption, we may experience lengthy delays in resuming production or distribution of affected products due to the need for regulatory approvals, and we may experience loss of market share, additional expense and harm to our reputation.

Our insurance program may not be adequate to cover future losses: We maintain third-party insurance to cover our exposure to certain property and casualty losses and are self-insured for claims and expenses related to other property and casualty losses, including product liability, intellectual property infringement and enforcement, environmental, and cybersecurity and data privacy losses. We manage a portion of our exposure to self-insured losses through a wholly-owned captive insurance company. Insurance coverage limits provided by third-party insurers and/or our captive insurance company may not be sufficient to fully cover certain losses we may experience.

We have experienced, and may continue to experience, a significant and unpredictable need to adjust our operations as market demand for certain of our products has shifted and continues to shift or as may be mandated by

governmental authorities: Some of our products are particularly sensitive to reductions in elective medical procedures. It is not possible to predict whether elective medical procedures will be suspended or reduced in the future and, to the extent individuals and customers are required to delay or cancel elective procedures, our business, cash flows, financial condition and results of operations could be negatively affected. Further, our customers have experienced, and may continue to experience, staffing shortages that may result in decreased demand for our products, which could negatively affect our business and financial results.

Unpredictable increases in demand for certain of our products have exceeded in the past, and could exceed in the future, our capacity to meet such demand timely, which could adversely affect our customer relationships and result in negative publicity. In this regard, the accelerated development and production of products and services to address medical and other requirements could increase the risk of regulatory enforcement actions, product defects or related claims or reputational harm, among other things.

Our use of AI and other emerging technologies could adversely impact our business and financial results: We have begun to deploy AI and other emerging technologies in various facets of our operations and we continue to explore further use cases. The rapid advancement of these technologies presents opportunities for us in research, manufacturing, commercialization, and other business endeavors, but also entails risks, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. In addition, any disruption or failure in the AI functionality we incorporate into our business activities, products or services could adversely impact our business or result in delays or errors in our product offerings. The legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity and privacy and data protection. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant costs on us and limit our ability to effectively develop, deploy or use AI technologies. Furthermore, if we are unable to effectively manage the use of AI technologies by our employees and service providers, our confidential information, intellectual property and reputation could be put at risk. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

Pandemics and public health emergencies, and the fear thereof, have in the past materially adversely affected and could in the future materially adversely affect, our operations, supply chain, manufacturing, product distribution, customers and other business activities: In connection with prior pandemics, governmental authorities and private enterprises implemented, and may in the future implement in connection with another pandemic or public health emergency (or in response to the fear thereof), measures, such as travel bans and restrictions, quarantines, shelter-in-place orders and shutdowns. Our customers, global suppliers, distributors and manufacturing facilities have in the past been, and could in the future be, materially affected by restrictive measures implemented in response to a pandemic or public health emergency, which has in the past caused and could in the future cause them to be unable to hire and retain employees, distribute or use our products or provide required services. We have as a result experienced, and could in the future experience, delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions, which may result in our inability to satisfy consumer demand for our products in a timely manner or at all and which could harm our reputation, future sales and profitability. The extent of any future pandemic or public health emergency's effect on our business and industry will depend on, among other things, the severity of the disease, the successful development, distribution and acceptance of vaccines for diseases, future resurgences and/or the spread of disease variants, all of which are uncertain and difficult to predict. The COVID-19 pandemic materially impacted us, and any future pandemic or public health emergency could materially impact us and would heighten many of the other risks described in this report.

LEGAL AND REGULATORY RISKS

Current economic and political conditions make tax rules in jurisdictions subject to significant change: Our future results of operations could be affected by changes in the effective tax rate as a result of changes in tax laws, regulations and judicial rulings. We are continuing to evaluate the impact of tax reform in the countries in which we operate as new guidance is published and new regulations are adopted. In addition, further changes in the tax laws could arise, including as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Cooperation and Development (OECD). The OECD, which represents a coalition of member countries, has put forth two proposed frameworks that revise the existing profit allocation and nexus rules (Pillar 1) and ensure a minimal level of taxation (Pillar 2), respectively. In 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws are effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes, could increase tax expense in future periods.

We could be negatively impacted by future changes in the allocation of income to each of the income tax jurisdictions in which we operate: We operate in multiple income tax jurisdictions both in the United States and internationally. Accordingly, our management must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Income tax authorities regularly perform audits of our income tax filings. Income tax audits associated with the allocation of income and other complex issues, including inventory transfer pricing and cost sharing, product royalty and foreign branch arrangements, may require an extended period to resolve and may result in significant income tax adjustments.

The impact of healthcare reform legislation on our business remains uncertain: Several markets where we sell our products are making efforts to expand access to healthcare or health insurance coverage while decreasing costs. These efforts may have a direct or unintended negative impact on access to medical technology and could have a significant effect on our business. Both in the U.S. and internationally, governmental authorities may make legislative or administrative reforms to existing reimbursement programs, make adverse decisions relating to our

products' coverage or reimbursement, or make changes to patient access to healthcare, all of which could adversely impact the demand for and usage of our products or the prices that our customers are willing to pay for them. We cannot predict what healthcare programs and regulations could ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business. Similarly, we cannot predict the impact that healthcare reform legislation in other countries where we sell our products may have on our business.

We are subject to extensive governmental regulation relating to the classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products: The classification, manufacturing, sterilization, licensing, labeling, marketing and sale of our products are subject to extensive and evolving regulations and rigorous regulatory enforcement by the FDA, state governments, European Union and other governmental authorities in the United States and internationally. These governmental authorities may impose additional requirements or limits on the methods, procedures or agents we use to manufacture and sterilize our products, which could have a negative impact on our business. For example, governmental authorities in the United States and internationally have or are considering adopting regulations on the use of per- and polyfluoroalkyl substances. In addition, the process of obtaining licenses, regulatory clearances and/or approvals to market and sell our products can be costly and time consuming and the clearances and/or approvals might not be granted timely. We have ongoing responsibilities under the laws and regulations applicable to the manufacturing of products within our facilities and those contracted by third parties that are subject to periodic inspections by the FDA, state Boards of Pharmacy and other governmental authorities to determine compliance with the quality system, medical device reporting regulations and other requirements. We may also be subject to legal obligations in some countries that require disclosure or sharing of proprietary information. We incur significant costs to comply with regulations, including the MDR. If we fail to comply with applicable regulatory requirements, we may be subject to a range of sanctions, including substantial fines, warning letters that require corrective action, product seizures, recalls, import restrictions, the suspension of product manufacturing or sales, revocation of approvals, exclusion from future participation in government healthcare programs, substantial fines and criminal prosecution.

We are subject to federal, state and foreign healthcare regulations, including anti-bribery, anti-corruption, anti-kickback and false claims laws, globally and could face substantial penalties if we fail to comply with such regulations and laws: The relationships that we, and third parties that market and/or sell our products, have with healthcare professionals, such as physicians, hospitals, healthcare organizations and others, are subject to scrutiny under various state and federal laws often referred to collectively as healthcare fraud and abuse laws. In addition, the United States and foreign government regulators have increased the enforcement of the Foreign Corrupt Practices Act (FCPA) and other anti-bribery and anti-kickback laws. We also must comply with a variety of other laws that impose extensive tracking and reporting related to all transfers of value provided to certain healthcare professionals and others. These laws and regulations are broad in scope and are subject to evolving interpretation and we have in the past been, and in the future could be, required to incur substantial costs to investigate, audit and monitor compliance or to alter our practices. Violations or alleged violations of these laws have in the past resulted and could in the future result in investigations, litigation or government proceedings, and we have been and may in the future be subject to criminal or civil penalties and sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs. For example, in 2013 and 2018 we settled claims brought by the SEC related to the FCPA. Pursuant to these settlements, we paid fines and penalties and retained an independent compliance consultant. We continue to implement recommendations that resulted from the independent compliance consultant's review of our commercial practices to enhance our commercial business practices. In addition, we are currently investigating whether certain business activities in certain foreign countries violated provisions of the FCPA and have been contacted by the SEC, United States Department of Justice and certain other regulatory authorities. Although we are currently unable to predict the outcome of the investigations or the potential impact, if any, on our financial statements, the impacts could potentially be significant.

We are subject to privacy, data protection and data security regulations and laws globally, and could face substantial penalties if we fail to comply with such regulations and laws: We are subject to a variety of laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personally identifiable healthcare information. For example, in the United States, privacy and security regulations under the Health Insurance Portability and Accountability Act of 1996, including the expanded requirements under the Health Information Technology for Economic and Clinical Health Act of 2009, establish comprehensive standards with respect to the use and disclosure of protected health information (PHI), by covered entities, in addition to setting standards to protect the confidentiality, integrity and security of PHI. Regulators are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the European Union's General Data Protection Regulation (GDPR) established rules regarding the handling of personal data. Non-compliance with the GDPR may result in monetary penalties of up to 4% of total company revenue. Various U.S. states and other governmental authorities around the world have imposed or are considering similar types of laws and regulations, data breach reporting and penalties for non-compliance and increasing security requirements. These laws and regulations are broad in scope and are subject to evolving interpretation and enforcement and we have in the past been, and in the future could be, required to incur substantial costs to monitor compliance or to alter our practices. As new privacy-related laws and regulations are implemented, the time and resources needed for us to comply with such laws and regulations, as well as our potential liability for non-compliance and reporting obligations in the case of data breaches, have increased and may further increase.

We may be adversely affected by product liability claims, unfavorable court decisions or legal settlements: We are exposed to potential product liability risks inherent in the design, manufacture and marketing of medical devices, many of which are implanted in the human body for long periods of time or indefinitely. We are currently defendants in a number of product liability matters, including those relating to our Rejuvenate and ABGII Modular-Neck hip stems, LFIT Anatomic CoCr V40 Femoral Heads and the product liability lawsuits and claims relating to Wright Medical Group N.V. (Wright) legacy hip products discussed in Note 7 to our Consolidated Financial

Statements. These matters are subject to uncertainties and outcomes are not predictable. Further, the European Representative Actions Directive (the Collective Redress Directive) mandates a class action regime in each EU member state to facilitate domestic and cross-border class actions in a wide range of areas, including product liability claims with medical devices. The European Product Liability Directive was revised in 2024 and will become fully adopted into each member state's national laws by 2026. The revised Product Liability Directive and Collective Redress Directive exposes us to additional litigation risks and could result in significant legal expenses. In addition, we may incur significant legal expenses or reputational damage for product liability claims regardless of whether we are found to be liable.

Intellectual property litigation and infringement claims could cause us to incur significant expenses or prevent us from selling certain of our products: The medical device industry is characterized by extensive intellectual property litigation and, from time to time, we are the subject of claims of infringement or misappropriation. Regardless of the outcome, such claims are expensive to defend and divert management and operating personnel from other business issues. A successful claim or claims of patent or other intellectual property infringement against us could result in payment of significant monetary damages and/or royalty payments or negatively impact our ability to sell current or future products in the affected category.

Dependence on intellectual proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may impact offerings in our product portfolios: Our long-term success largely depends on our ability to market technologically competitive products. If we fail to obtain or maintain adequate intellectual property protection, it could allow others to sell products that directly compete with proprietary features in our product portfolio. Also, our issued patents may be subject to claims challenging their validity and scope and raising other issues. In addition, currently pending or future patent applications may not result in issued patents and the expiration of patents may lead to a loss of exclusive rights and/or increased competition.

MARKET RISKS

We have exposure to exchange rate fluctuations on cross border transactions and translation of local currency results into United States Dollars: We report our financial results in United States Dollars and approximately 25% of our net sales are denominated in foreign currencies, including the Australian Dollar, British Pound, Canadian Dollar, Euro and Japanese Yen. Cross border transactions with external parties, financing transactions in currencies other than the United States Dollar and intercompany relationships result in increased exposure to foreign currency exchange effects. While we use derivative instruments to manage the impact of currency exchange, our hedging strategies may not be successful, and our unhedged exposures continue to be subject to currency fluctuations. In addition, the weakening or strengthening of the United States Dollar results in favorable or unfavorable translation effects when the results of our foreign locations are translated into United States Dollars. In recent years, currency exchange rates have been especially volatile, and these currency fluctuations have affected, and may continue to affect, our results of operations.

Additional capital that we may require in the future may not be available to us or may only be available to us on unfavorable terms, which could negatively affect our liquidity: Our future capital requirements will depend on many factors, including operating requirements, current and future acquisitions and the need to refinance existing debt. Our ability to issue additional debt or enter into other financing arrangements on acceptable terms could be adversely affected by our debt levels, unfavorable changes in economic conditions or uncertainties that affect the capital markets. Changes in credit ratings issued by nationally recognized credit rating agencies could also adversely affect our access to and cost of financing. Higher borrowing costs or the inability to access capital markets could adversely affect our ability to support future growth and operating requirements. In addition, we have experienced, and could in the future experience, loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers and suppliers facing liquidity issues due to the current macroeconomic environment, type and number of conditions being treated or for other reasons. As a result, we may be compelled to take additional measures to preserve our cash flow, including through the reduction of operating expenses or suspension of dividend payments.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE RISKS

We could be negatively impacted by corporate responsibility and sustainability-related matters: Governments, investors, customers, employees and other stakeholders have been focused on corporate responsibility practices and disclosures, and expectations in this area continue to rapidly evolve, including in diverging directions. On occasion, we announce new initiatives and make disclosures, including goals, under our corporate responsibility framework. This framework is aligned with our areas of interest and applicable regulatory requirements, which include environment and sustainability, workforce-related issues, diversity, equity and inclusion and supply chain management, among others. Implementation of these initiatives involves risks and uncertainties, requires investments and depends in part on third-party performance or data that is outside our control. We cannot guarantee that we will achieve our announced corporate responsibility initiatives. The criteria by which our corporate responsibility practices are assessed may change due to the quickly evolving landscape, which could result in greater regulatory requirements or expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Moreover, the increasing attention to corporate responsibility initiatives could also result in, among other things, reduced demand for our products, reduced profits, increased investigations and litigation and an increased risk of reputational damage. If we are unable to satisfy evolving criteria, certain investors and other stakeholders may conclude that our policies and/or actions with respect to corporate responsibility matters are inadequate or undesirable. If we fail or are perceived to have failed to achieve previously announced initiatives or goals, comply with corporate responsibility laws and regulations, meet evolving expectations or accurately disclose our progress, we could face legal and regulatory proceedings and our reputation, business, financial condition and results of operations could be adversely impacted.

Physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results: Risks associated with climate change are subject to increasing societal, regulatory and political focus in the United States and globally. Shifts in weather patterns caused by climate change have increased and are expected to further increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures and flooding, which could cause more significant business and supply chain

interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, increased costs of raw materials and components, increased liabilities and decreased revenues than what we have experienced in the past from such events. In addition, increased public concern over climate change has resulted in certain, and could result in additional, new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material availability and sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

RISK MANAGEMENT AND STRATEGY

We review cybersecurity risk as part of our overall enterprise risk management program. This ensures that cybersecurity risk management remains a top priority in our business strategy and operations.

MANAGEMENT'S ROLE IN MANAGING RISK

Primary management responsibility for assessing, monitoring and managing our cybersecurity risks rests with our chief information security officer ("CISO"). Our current CISO has over 30 years of experience in information technology including over 20 years in cybersecurity and oversees a team of cybersecurity professionals with over 140 security, risk, and compliance certifications. The CISO is regularly informed about recent developments in cybersecurity, including potential threats and innovative risk management techniques.

The CISO implements and oversees processes for the regular monitoring of our information systems. We use various tools and methodologies to manage cybersecurity risk that are tested regularly. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. In addition, we engage third-party consultants to conduct annual cybersecurity assessments and to conduct audits for compliance with regulatory, Sarbanes-Oxley Act, Service Organization Control Type 2 and International Organization for Standardization standards. We also engage third parties to assess our cybersecurity maturity and risk management programs.

We use a cross-departmental approach to addressing cybersecurity risk, with our cybersecurity, product security and legal teams presenting quarterly on key topics to a committee of leaders in finance, regulatory, and corporate affairs functions. This leadership committee meets quarterly to ensure that we have input and oversight from critical stakeholders into our cybersecurity program and evolving issues.

The CISO oversees a training and awareness program for employees to take part in protecting the Company against cybersecurity risks. We have implemented annual mandatory security education to help employees understand cybersecurity risks and comply with our cybersecurity policies. Additionally, we provide frequent communications around pertinent cybersecurity topics and policies to all employees. We also provide additional cybersecurity and data protection training to employees in certain roles.

As part of our cybersecurity risk management program, we also conduct cybersecurity and privacy assessments on all third parties who integrate with Stryker's data, network, systems and products. We use a combination of internal and external tools to confirm that these third parties meet our security requirements. We leverage standard industry threat model and privacy impact assessment concepts to confirm that data minimization and adequate data protections are in place. We perform supplemental reviews as necessary, commensurate with the risk associated with each vendor.

In the event of a cybersecurity incident, we have an incident response plan that includes immediate actions to mitigate the impact and long-term strategies for remediation and prevention of future incidents. The cybersecurity and product security teams routinely practice this plan with functions across the organization. We conduct tabletop exercises with senior management, during which we practice the procedures in place to ensure that potentially material cybersecurity risks and incidents are escalated to management and the Board of Directors where applicable.

GOVERNANCE

Cybersecurity risks are overseen by the full Board of Directors and the Audit Committee. The Audit Committee is central to the Board of Directors' oversight of cybersecurity risks and bears the primary responsibility for overseeing cybersecurity risk. The Audit Committee actively participates in strategic decisions related to cybersecurity, offering guidance and approval for major cybersecurity initiatives. This involvement ensures that cybersecurity considerations are integrated into our broader strategic objectives.

Our CISO provides comprehensive updates to the Audit Committee quarterly and the full Board of Directors periodically. These briefings include a range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events;
- Metrics demonstrating company and industry-standard prevention of common threats; and
- Regulatory changes impacting cybersecurity requirements and strategy.

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats and is actively engaged in our cybersecurity risk management strategy.

RISKS FROM CYBERSECURITY THREATS

Although cybersecurity risks have not materially affected us, including our business strategy, results of operations or financial condition, to date, we face numerous and evolving cybersecurity threats in our business. For more information about the cybersecurity risks we face, see the risk factor entitled "We, our business partners or our third-party vendors could experience a material failure or breach of a key information technology system, network, process or site" in Item 1A. Risk Factors.

ITEM 2. PROPERTIES.

We have approximately 27 company-owned and 297 leased locations worldwide including 45 manufacturing locations. We believe that our properties are in good operating condition and adequate for the manufacture and distribution of our products.

We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

ITEM 3. LEGAL PROCEEDINGS.

We are involved in various ongoing proceedings, legal actions and claims arising in the normal course of our business, including proceedings related to product, labor, intellectual property and other matters. Refer to Note 7 to our Consolidated Financial Statements for further information.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the New York Stock Exchange under the symbol SYK.

Our Board of Directors considers payment of cash dividends at its quarterly meetings. On January 31, 2025 there were 2,510 shareholders of record of our common stock.

We did not repurchase any shares in the three months ended December 31, 2024 and the total dollar value of shares that could be acquired under our authorized repurchase program at December 31, 2024 was $1,033.

In the fourth quarter 2024 we did not issue shares of our common stock as performance incentive awards to employees. When issued, these shares are not registered under the Securities Act of 1933 based on the conclusion that the awards are not events of sale within the meaning of Section 2(a)(3) of the Act.

The following graph compares our total returns (including reinvestment of dividends) against the Standard & Poor's (S&P) 500 Index and the S&P 500 Health Care Index. The graph assumes $100 (not in millions) invested on December 31, 2019 in our common stock and each of the indices.



Company / Index	2019	2020	2021	2022	2023	2024
Stryker Corporation	**$ 100.00**	**$ 118.17**	**$ 130.25**	**$ 120.59**	**$ 149.29**	**$ 181.15**
S&P 500 Index	$ 100.00	$ 118.40	$ 152.39	$ 124.79	$ 157.59	$ 197.02
S&P 500 Health Care Index	$ 100.00	$ 113.45	$ 143.09	$ 140.29	$ 143.18	$ 146.87

ITEM 6. SELECTED FINANCIAL DATA.

Statement of Earnings Data	2024	2023	2022	2021	2020
Net sales	$ 22,595	$ 20,498	$ 18,449	$ 17,108	$ 14,351
Cost of sales	8,155	7,440	6,871	6,140	5,294
Gross profit	$ 14,440	$ 13,058	$ 11,578	$ 10,968	$ 9,057
Research, development and engineering expenses	1,466	1,388	1,454	1,235	984
Selling, general and administrative expenses	7,685	7,111	6,386	6,266	5,163
Amortization of intangible assets	623	635	627	619	472
Goodwill and other impairments	977	36	270	264	215
Total operating expenses	$ 10,751	$ 9,170	$ 8,737	$ 8,384	$ 6,834
Operating income	$ 3,689	$ 3,888	$ 2,841	$ 2,584	$ 2,223
Other income (expense), net	(197)	(215)	(158)	(303)	(269)
Earnings before income taxes	$ 3,492	$ 3,673	$ 2,683	$ 2,281	$ 1,954
Income taxes	499	508	325	287	355
Net earnings	$ 2,993	$ 3,165	$ 2,358	$ 1,994	$ 1,599
Net earnings per share of common stock:					
Basic	$ 7.86	$ 8.34	$ 6.23	$ 5.29	$ 4.26
Diluted	$ 7.76	$ 8.25	$ 6.17	$ 5.21	$ 4.20
Dividends declared per share of common stock	$ 3.240	$ 3.050	$ 2.835	$ 2.585	$ 2.355
Balance Sheet Data					
Cash, cash equivalents and current marketable securities	$ 3,743	$ 3,053	$ 1,928	$ 3,019	$ 3,024
Accounts receivable, net	3,987	3,765	3,565	3,022	2,701
Inventories	4,774	4,843	3,995	3,314	3,494
Property, plant and equipment, net	3,448	3,215	2,970	2,833	2,752
Total assets	$ 42,971	$ 39,912	$ 36,884	$ 34,631	$ 34,330
Accounts payable	1,679	1,517	1,413	1,129	810
Total debt	13,597	12,995	13,048	12,479	13,991
Shareholders' equity	$ 20,634	$ 18,593	$ 16,616	$ 14,877	$ 13,084
Cash Flow Data					
Net cash provided by operating activities	$ 4,242	$ 3,711	$ 2,624	$ 3,263	$ 3,277
Purchases of property, plant and equipment	755	575	588	525	487
Depreciation	427	393	371	371	340
Acquisitions, net of cash acquired	1,628	390	2,563	339	4,222
Amortization of intangible assets	623	635	627	619	472
Payments of dividends	1,219	1,139	1,051	950	863
Repurchase of common stock	—	—	—	—	—
Other Data					
Number of shareholders of record	2,520	2,518	2,533	2,551	2,597
Approximate number of employees	53,000	52,000	51,000	46,000	43,000

Dollar amounts in millions except per share amounts or as otherwise specified.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

About Stryker

Stryker is a global leader in medical technologies and, together with our customers, we are driven to make healthcare better. We offer innovative products and services in MedSurg, Neurotechnology, and Orthopaedics that help improve patient and healthcare outcomes. Alongside our customers around the world, we impact more than 150 million patients annually. Our goal is to achieve sales growth at the high-end of the medical technology (MedTech) industry and maintain our long-term capital allocation strategy that prioritizes: (1) Acquisitions, (2) Dividends and (3) Share repurchases.

Overview of 2024

In 2024 we achieved reported net sales growth of 10.2%. Excluding the impact of acquisitions and divestitures, sales grew 10.2% in constant currency. We reported net earnings of $2,993 and net earnings per diluted share of $7.76. Excluding the impact of certain items, we achieved adjusted net earnings[1] of $4,700 and adjusted net earnings per diluted share[1] of $12.19 representing growth of 15.0%.

We continued our capital allocation strategy by investing $1,628 in acquisitions and paying $1,219 in dividends to our shareholders.

In 2024 we completed various acquisitions for total consideration of $1,628 in upfront payments, net of cash acquired, as well as $400 of contingent consideration if certain commercial or clinical milestones are achieved. Refer to Note 6 to our Consolidated Financial Statements for further information.

In May 2024 we repaid the outstanding $600 principal amount of the 3.375% senior unsecured notes due May 15, 2024. In September 2024 we issued $750 of 4.250% senior unsecured notes due September 11, 2029, €800 of 3.375% senior unsecured notes due September 11, 2032, $750 of 4.625% senior unsecured notes due September 11, 2034 and €600 of 3.625% senior unsecured notes due September 11, 2036. In November 2024 we repaid the outstanding €500 of floating rate senior notes and in December 2024 we repaid €850 of 0.250% senior unsecured notes.

[1] Refer to "Non-GAAP Financial Measures" for a discussion of non-GAAP financial measures used in this report and a reconciliation to the most directly comparable GAAP financial measure.

CONSOLIDATED RESULTS OF OPERATIONS

				Percent Net Sales			Percentage Change	
	2024	2023	2022	2024	2023	2022	2024 vs. 2023	2023 vs. 2022
Net sales	$ 22,595	$ 20,498	$ 18,449	100.0 %	100.0 %	100.0 %	10.2 %	11.1 %
Gross profit	14,440	13,058	11,578	63.9	63.7	62.8	10.6	12.8
Research, development and engineering expenses	1,466	1,388	1,454	6.5	6.8	7.9	5.6	(4.5)
Selling, general and administrative expenses	7,685	7,111	6,386	34.0	34.7	34.6	8.1	11.4
Amortization of intangible assets	623	635	627	2.8	3.1	3.4	(1.9)	1.3
Goodwill and other impairments	977	36	270	4.3	0.2	1.5	nm	nm
Other income (expense), net	(197)	(215)	(158)	(0.9)	(1.0)	(0.9)	(8.4)	36.1
Income taxes	499	508	325	nm	nm	nm	(1.8)	56.3
Net earnings	$ 2,993	$ 3,165	$ 2,358	13.2 %	15.4 %	12.8 %	(5.4)%	34.2 %
Net earnings per diluted share	$ 7.76	$ 8.25	$ 6.17				(5.9)%	33.7 %
Adjusted net earnings per diluted share[1]	$ 12.19	$ 10.60	$ 9.34				15.0 %	13.5 %

nm - not meaningful

Geographic and Segment Net Sales				Percentage Change			
				2024 vs. 2023		2023 vs. 2022	
	2024	2023	2022	As Reported	Constant Currency	As Reported	Constant Currency
Geographic:							
United States	$ 16,943	$ 15,257	$ 13,638	11.0 %	11.0 %	11.9 %	11.9 %
International	5,652	5,241	4,811	7.9	9.8	8.9	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %
Segment:							
MedSurg and Neurotechnology	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	11.7 %	12.2 %
Orthopaedics	9,077	8,335	7,556	8.9	9.4	10.3	10.9
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.1 %	11.6 %

Supplemental Net Sales Growth Information

	2024	2023	2022	Percentage Change 2024 vs. 2023 As Reported	2024 vs. 2023 Constant Currency	2024 vs. 2023 United States As Reported	2024 vs. 2023 International As Reported	2024 vs. 2023 International Constant Currency	2023 vs. 2022 As Reported	2023 vs. 2022 Constant Currency	2023 vs. 2022 United States As Reported	2023 vs. 2022 International As Reported	2023 vs. 2022 International Constant Currency
MedSurg and Neurotechnology:													
Instruments	$ 2,834	$ 2,534	$ 2,245	11.9 %	12.1 %	12.5 %	9.5 %	10.6 %	12.9 %	13.0 %	13.5 %	10.4 %	11.8 %
Endoscopy	3,388	3,068	2,759	10.5	11.0	11.1	7.7	10.7	11.2	11.7	11.9	8.0	9.9
Medical	3,852	3,459	3,031	11.4	11.7	14.6	(2.0)	(0.3)	14.1	14.4	15.0	10.7	12.3
Neurovascular	1,307	1,226	1,200	6.6	8.2	4.7	7.9	10.5	2.2	4.0	8.3	(1.5)	1.5
Neuro Cranial	2,136	1,876	1,658	13.9	14.1	15.0	8.7	10.2	13.1	13.4	12.7	15.4	16.8
	$ 13,518	$ 12,163	$ 10,893	11.1 %	11.6 %	12.7 %	5.9 %	7.9 %	11.7 %	12.2 %	13.1 %	7.2 %	9.2 %
Orthopaedics:													
Knees	$ 2,447	$ 2,273	$ 1,997	7.6 %	8.2 %	6.7 %	10.4 %	12.2 %	13.8 %	14.4 %	12.3 %	18.5 %	20.9 %
Hips	1,704	1,544	1,413	10.3	11.3	7.2	15.9	18.4	9.3	10.4	10.3	7.5	10.7
Trauma and Extremities	3,507	3,147	2,807	11.4	11.6	12.6	8.3	9.1	12.1	12.2	12.9	10.1	10.5
Spinal Implants	707	713	733	(0.7)	(0.3)	(2.1)	2.5	3.8	(2.7)	(2.0)	(2.2)	(4.1)	(3.4)
Other	712	658	606	8.1	9.6	7.3	10.1	15.4	8.6	9.5	2.9	25.8	32.3
	$ 9,077	$ 8,335	$ 7,556	8.9 %	9.4 %	8.4 %	10.2 %	12.0 %	10.3 %	10.9 %	10.0 %	11.1 %	13.1 %
Total	$ 22,595	$ 20,498	$ 18,449	10.2 %	10.7 %	11.0 %	7.9 %	9.8 %	11.1 %	11.6 %	11.9 %	8.9 %	10.9 %

Note: In the fourth quarter 2024 we reorganized our Spine business to align with certain updates to our internal reporting structure. The spine enabling technologies portfolio (Enabling Technologies) was reclassified to Other Orthopaedics, the interventional spine portfolio was reclassified to Neuro Cranial and the remaining Spine business was renamed to Spinal Implants. Neuro Cranial includes sales related to interventional spine of $413, $327 and $282 for 2024, 2023 and 2022. Other Orthopaedics includes sales related to Enabling Technologies of $152, $149 and $131 for 2024, 2023 and 2022. In the first quarter 2024 a product line previously included in Instruments has been reclassified to Endoscopy to align with a change in our internal reporting structure. We have reflected these changes in all historical periods presented.

Consolidated Net Sales

Consolidated net sales in 2024 increased 10.2% as reported and 10.7% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.5% impact of acquisitions and divestitures, net sales in constant currency increased by 9.1% from increased unit volume and 1.1% due to higher prices. The unit volume increase was primarily due to higher shipments across all businesses.

Consolidated net sales in 2023 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 10.9% from increased unit volume and 0.6% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses and most Orthopaedics businesses.

MedSurg and Neurotechnology Net Sales

MedSurg and Neurotechnology net sales in 2024 increased 11.1% as reported and 11.6% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.4% impact of acquisitions and divestitures, net sales in constant currency increased by 9.5% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

MedSurg and Neurotechnology net sales in 2023 increased 11.7% as reported and 12.2% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.3% impact of acquisitions and divestitures, net sales in constant currency increased by 10.2% from increased unit volume and 1.7% due to higher prices. The unit volume increase was due to higher shipments across all MedSurg and Neurotechnology businesses.

Orthopaedics Net Sales

Orthopaedics net sales in 2024 increased 8.9% as reported and 9.4% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.5%. Excluding the 0.7% impact of acquisitions and divestitures, net sales in constant currency increased by 8.7% from increased unit volume. The unit volume increase was due to higher shipments across all Orthopaedics businesses.

Orthopaedics net sales in 2023 increased 10.3% as reported and 10.9% in constant currency, as foreign currency exchange rates negatively impacted net sales by 0.6%. Excluding the 0.1% impact of acquisitions and divestitures, net sales in constant currency increased by 11.9% from increased unit volume partially offset by 1.1% due to lower prices. The unit volume increase was due to higher shipments across most Orthopaedics businesses.

Gross Profit

Gross profit was $14,440, $13,058 and $11,578 in 2024, 2023, and 2022. The key components of the change were:

	Gross Profit Percent Net Sales
2022	**62.8 %**
Sales pricing	20 bps
Volume and mix	100 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	10 bps
2023	**63.7 %**
Sales pricing	40 bps
Volume and mix	60 bps
Manufacturing and supply chain costs	(40) bps
Inventory stepped up to fair value	(20) bps
Structural optimization and other special charges	(20) bps
2024	**63.9 %**

Gross profit as a percentage of net sales increased to 63.9% in 2024 from 63.7% in 2023 due to higher sales pricing and favorable volume partially offset by higher manufacturing and supply chain costs primarily due to inflationary pressures impacting fixed and variable manufacturing costs as well as higher amortization of inventory stepped up to fair value.

Gross profit as a percentage of net sales increased to 63.7% in 2023 from 62.8% in 2022 due to higher sales pricing and favorable volume offset by higher manufacturing and supply chain costs primarily due to higher raw material costs in the first six months of 2023 and supply chain inefficiencies.

While segment mix was not a significant driver of the change in gross profit as a percent of net sales between 2024, 2023 and 2022, we generally expect segment mix to have an unfavorable impact for the foreseeable future as we anticipate more rapid sales growth in our lower gross margin MedSurg and Neurotechnology segment than our Orthopaedics segment.

Research, Development and Engineering Expenses

Research, development and engineering expenses as a percentage of net sales in 2024 decreased to 6.5% from 6.8% in 2023 primarily due to lower spend on medical device regulations in the European Union.

Research, development and engineering expenses as a percentage of net sales in 2023 decreased to 6.8% from 7.9% in 2022 primarily due to increased spending for product launches, the write-off of certain intangible assets and higher spend related to the new medical device regulations in the European Union in 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses as a percentage of net sales in 2024 decreased to 34.0% from 34.7% in 2023 primarily due to continued spend discipline and lower charges for structural optimization and certain legal matters partially offset by higher acquisition-related costs.

Selling, general and administrative expenses as a percentage of net sales in 2023 of 34.7% remained relatively flat with 34.6% in 2022 as charges of $132 related to share-based awards for Vocera employees that vested upon our acquisition in 2022 were partially offset by disciplined increases in spend and investments in 2023 to support our growth, including sales growth incentives and increased spend on travel and meetings. In addition, in 2022 we determined that certain commercial and regulatory milestones related to technology acquired in the purchase of Mobius Imaging and Cardan Robotics were no longer probable of being achieved and recorded $110 to reduce the fair value of contingent consideration.

Amortization of Intangible Assets

Amortization of intangible assets was $623, $635 and $627 in 2024, 2023 and 2022. These amounts include amortization related to intangible assets acquired in 2024 from various acquisitions, 2023 from Cerus Endovascular Limited (Cerus) and 2022 from Vocera. Refer to Notes 6 and 8 to our Consolidated Financial Statements for further information.

Goodwill and Other Impairments

In 2024 and 2022 we recorded goodwill impairment charges of $456 and $216 related to our Spine business.

In 2024 we recognized an estimated loss of $362 as a result of classifying certain assets in our Spinal Implants business as held for sale. Refer to Notes 8, 16 and 17 to our Consolidated Financial Statements for further information.

In 2024, 2023 and 2022 we recorded other impairments of $159, $36 and $54. Refer to Notes 15 and 16 to our Consolidated Financial Statements for further information.

Operating Income

Operating income was $3,689, $3,888 and $2,841 in 2024, 2023 and 2022. Operating income decreased as a percentage of sales to 16.3% in 2024 from 19.0% in 2023 and increased from 15.4% in 2022. Refer to the comments above for discussion of the primary drivers of the change.

MedSurg and Neurotechnology operating income as a percentage of net sales increased to 29.6% in 2024 from 28.5% in 2023. MedSurg and Neurotechnology operating income as a percentage of net sales increased to 28.5% in 2023 from 26.0% in 2022. Orthopaedics operating income as a percentage of net sales increased to 28.5% in 2024 from 27.2% in 2023. Orthopaedics operating income as a percentage of net sales increased to 27.2% in 2023 from 29.1% in 2022. The key components of the change were:

	Operating Income Percent Net Sales	
	MedSurg and Neurotechnology	Orthopaedics
2022	**26.0 %**	**29.1 %**
Sales pricing	70 bps	(30) bps
Volume	100 bps	80 bps
Manufacturing and supply chain costs	90 bps	(220) bps
Research, development and engineering expenses	50 bps	20 bps
Selling, general and administrative expenses	(60) bps	(40) bps
2023	**28.5 %**	**27.2 %**
Sales pricing	70 bps	0 bps
Volume	40 bps	70 bps
Manufacturing and supply chain costs	(40) bps	(20) bps
Research, development and engineering expenses	0 bps	10 bps
Selling, general and administrative expenses	40 bps	70 bps
2024	**29.6 %**	**28.5 %**

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2024 from 2023 was primarily driven by higher unit volumes, higher prices and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The increase in MedSurg and Neurotechnology operating income as a percentage of net sales in 2023 from 2022 was primarily driven by higher unit volumes, higher prices and lower manufacturing and supply chain costs due to supply chain challenges impacting capital products in our MedSurg businesses in 2022 which improved in 2023 partially offset by higher selling, general and administrative expenses as a percentage of sales due to continued investments including sales growth incentives and a more normalized cadence of travel and meetings.

The increase in Orthopaedics operating income as a percentage of net sales for 2024 from 2023 was primarily driven by higher sales volumes and a decrease in selling, general and administrative expenses as a percentage of sales partially offset by higher manufacturing and supply chain costs.

The decrease in Orthopaedics operating income as a percentage of net sales for 2023 from 2022 was primarily driven by higher higher manufacturing and supply chain costs primarily due to increased inventory reserves partially offset by higher unit volumes.

Other Income (Expense), Net

Other income (expense), net was ($197), ($215) and ($158) in 2024, 2023 and 2022. The decrease in net expense in 2024 from 2023 was primarily due to higher interest income partially offset by lower interest expense in 2024. The increase in net expense in 2023 from 2022 was primarily due to the release of accrued interest of $50 in 2022 related to the effective settlement of the United States federal income tax audit for years 2014 through 2018. Refer to Note 11 to our Consolidated Financial Statements for further information and higher interest income in 2023.

Income Taxes

Our effective tax rate was 14.3%, 13.8% and 12.1% for 2024, 2023 and 2022. The effective income tax rate for 2024 decreased from 2023 due to the 2024 deferred tax benefit on the outside basis difference related to the anticipated sale of the Spinal Implants business partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. The effective income tax rate for 2023 increased from 2022 due to the 2022 effective settlement of the United States federal income tax audit for years 2014 through 2018 and the 2022 reversal of deferred income tax on undistributed earnings of foreign subsidiaries partially offset by the 2023 tax effect related to transfers of intellectual property between tax jurisdictions. Additionally, the effective income tax rates for 2024, 2023 and 2022 reflect the continued lower effective income tax rates as a result of our European operations and certain discrete tax items.

The Organisation for Economic Cooperation and Development (OECD), which represents a coalition of member countries, has put forth two proposed base erosion and profit shifting frameworks that revise the existing profit allocation and nexus rules (Pillar One) and ensure a minimal level of taxation (Pillar Two). On December 12, 2022 the European Union member states agreed to implement the Inclusive Framework's global corporate minimum tax rate of 15%, and various countries within and outside the European Union have either enacted or proposed new tax laws implementing Pillar Two in 2024. The OECD continues to release additional guidance and we anticipate more countries will enact similar tax laws. Some of the new tax laws became effective in 2024 while others will be effective in future years. These tax law changes and any additional contemplated tax law changes could increase tax expense in future periods.

Net Earnings

Net earnings for 2024 increased to $2,993 or $7.76 per diluted share from $3,165 or $8.25 per diluted share in 2023 and $2,358 or $6.17 per diluted share in 2022. Refer to the comments above for discussion of the primary drivers of the change.

Non-GAAP Financial Measures

We supplement the reporting of our financial information determined under accounting principles generally accepted in the United States (GAAP) with certain non-GAAP financial measures, including percentage sales growth in constant currency; percentage organic sales growth; adjusted gross profit; adjusted selling, general and administrative expenses; adjusted research, development and engineering expenses; adjusted operating income; adjusted other income (expense), net; adjusted income taxes; adjusted effective income tax rate; adjusted net earnings; and adjusted net earnings per diluted share (Diluted EPS). We believe these non-GAAP financial measures provide meaningful information to assist investors and shareholders in understanding our financial results and assessing our prospects for future performance. Management believes percentage sales growth in constant currency and the other adjusted measures described above are important indicators of our operations because they exclude items that may not be indicative of or are unrelated to our core operating results and provide a baseline for analyzing trends in our underlying businesses. Management uses these non-GAAP financial measures for reviewing the operating results of reportable business segments and analyzing potential future business trends in connection with our budget process and bases certain management incentive compensation on these non-GAAP financial measures. To measure percentage sales growth in constant currency, we remove the impact of changes in foreign currency exchange rates that affect the comparability and trend of sales. Percentage sales growth in constant currency is calculated by translating current and prior year results at the same foreign currency exchange rate. To measure percentage organic sales growth, we remove the impact of changes in foreign currency exchange rates, acquisitions and divestitures, which affect the comparability and trend of sales. Percentage organic sales growth is calculated by translating current year and prior year results at the same foreign currency exchange rates excluding the impact of acquisitions and divestitures. To measure earnings performance on a consistent and comparable basis, we exclude certain items that affect the comparability of operating results and the trend of earnings. The income tax effect of each adjustment was determined based on the tax effect of the jurisdiction in which the related pre-tax adjustment was recorded. These adjustments are irregular in timing and may not be indicative of our past and future performance. The following are examples of the types of adjustments that may be included in a period:

1. *Acquisition and integration-related costs.* Costs related to integrating recently acquired businesses (e.g., costs associated with the termination of sales relationships, employee retention and workforce reductions, manufacturing integration costs and other integration-related activities), changes in the fair value of contingent consideration, amortization of inventory stepped-up to fair value, specific costs (e.g., deal costs and costs associated with legal entity rationalization) related to the consummation of the acquisition process and legal entity rationalization and acquisition-related tax items.
2. *Amortization of purchased intangible assets.* Periodic amortization expense related to purchased intangible assets.
3. *Structural optimization and other special charges.* Costs associated with employee retention and workforce reductions, the closure or transfer of manufacturing and other facilities (e.g., site closure costs, contract termination costs and redundant employee costs during the work transfers), product line exits (primarily inventory, long-lived asset and specifically-identified intangible asset write-offs), certain long-lived and intangible asset write-offs and impairments and other charges.
4. *Medical device regulations.* Costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the new medical device reporting regulations and other requirements of the European Union.
5. *Recall-related matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve the Rejuvenate, LFIT V40, Wright legacy hip products and other product recalls.
6. *Regulatory and legal matters.* Changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters

and the amount of favorable awards from settlements.

7. *Tax matters.* Impact of accounting for certain significant and discrete tax items.

Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names. These adjusted financial measures should not be considered in isolation or as a substitute for reported sales growth, gross profit, selling, general and administrative expenses, research, development and engineering expenses, operating income, other income (expense), net, income taxes, effective income tax rate, net earnings and net earnings per diluted share, the most directly comparable GAAP financial measures. These non-GAAP financial measures are an additional way of viewing aspects of our operations when viewed with our GAAP results and the reconciliations to corresponding GAAP financial measures at the end of the discussion of Consolidated Results of Operations below. We strongly encourage investors and shareholders to review our financial statements and publicly-filed reports in their entirety and not to rely on any single financial measure.

The weighted-average diluted shares outstanding used in the calculation of adjusted net earnings per diluted share are the same as those used in the calculation of reported net earnings per diluted share for the respective period.

Reconciliation of the Most Directly Comparable GAAP Financial Measure to Non-GAAP Financial Measure

2024	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 14,440	$ 7,685	$ 1,466	$ 3,689	$ (197)	$ 499	$ 2,993	14.3 %	$ 7.76
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	46	—	—	46	—	12	34	0.2	0.09
Other acquisition and integration-related (a)	—	(107)	(1)	108	—	23	85	0.2	0.22
Amortization of purchased intangible assets	—	—	—	623	—	128	495	1.0	1.28
Structural optimization and other special charges (b)	59	(77)	(2)	138	1	29	110	0.3	0.29
Goodwill and other impairments (c)	—	—	—	977	—	125	852	(0.6)	2.21
Medical device regulations (d)	9	—	(49)	58	—	14	44	0.1	0.11
Recall-related matters (e)	11	(29)	—	40	—	10	30	0.1	0.08
Regulatory and legal matters (f)	—	(36)	—	36	—	7	29	0.1	0.08
Tax matters (g)	—	—	—	—	—	(28)	28	(0.9)	0.07
Adjusted	$ 14,565	$ 7,436	$ 1,414	$ 5,715	$ (196)	$ 819	$ 4,700	14.8 %	$ 12.19

2023	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 13,058	$ 7,111	$ 1,388	$ 3,888	$ (215)	$ 508	$ 3,165	13.8 %	$ 8.25
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	—	—	—	—	—	—	—	—	—
Other acquisition and integration-related (a)	—	(20)	—	20	—	(25)	45	(0.8)	0.12
Amortization of purchased intangible assets	—	—	—	635	—	132	503	1.2	1.31
Structural optimization and other special charges (b)	39	(130)	(1)	170	—	38	132	0.4	0.34
Goodwill and other impairments (c)	—	—	—	36	—	9	27	0.1	0.08
Medical device regulations (d)	2	—	(94)	96	—	22	74	0.2	0.19
Recall-related matters (e)	—	(18)	—	18	—	4	14	—	0.04
Regulatory and legal matters (f)	—	(92)	—	92	—	29	63	0.4	0.16
Tax matters (g)	—	—	—	—	(8)	(51)	43	(1.2)	0.11
Adjusted	$ 13,099	$ 6,851	$ 1,293	$ 4,955	$ (223)	$ 666	$ 4,066	14.1 %	$ 10.60

2022	Gross Profit	Selling, General & Administrative Expenses	Research, Development & Engineering Expenses	Operating Income	Other Income (Expense), Net	Income Taxes	Net Earnings	Effective Tax Rate	Diluted EPS
Reported	$ 11,578	$ 6,386	$ 1,454	$ 2,841	$ (158)	$ 325	$ 2,358	12.1 %	$ 6.17
Acquisition and integration-related costs:									
Inventory stepped-up to fair value	12	—	—	12	—	3	9	—	0.02
Other acquisition and integration-related (a)	—	(138)	—	138	—	34	104	0.6	0.27
Amortization of purchased intangible assets	—	—	—	627	—	132	495	1.7	1.30
Structural optimization and other special charges (b)	56	(152)	(87)	295	—	61	234	0.8	0.61
Goodwill and other impairments (c)	—	—	—	270	—	5	265	(1.2)	0.70
Medical device regulations (d)	3	—	(137)	140	—	25	115	0.2	0.30
Recall-related matters (e)	—	15	—	(15)	—	(3)	(12)	—	(0.03)
Regulatory and legal matters (f)	—	(76)	—	76	—	7	69	(0.2)	0.18
Tax matters (g)	—	—	—	—	(75)	(9)	(66)	0.1	(0.18)
Adjusted	$ 11,649	$ 6,035	$ 1,230	$ 4,384	$ (233)	$ 580	$ 3,571	14.1 %	$ 9.34

(a) Charges represent certain acquisition and integration-related costs associated with acquisitions, including:

	2024	2023	2022
Termination of sales relationships	$ 4	$ 5	$ 21
Employee retention and workforce reductions	22	6	33
Changes in the fair value of contingent consideration	8	(1)	(135)
Manufacturing integration costs	1	2	32
Stock compensation payments upon a change in control	22	—	132
Other integration-related activities	49	8	55
Adjustments to Operating Income	**$ 108**	**$ 20**	**$ 138**
Charges for acquisition-related tax provisions	—	—	—
Other income taxes related to acquisition and integration-related costs	23	(25)	34
Adjustments to Income Taxes	**$ 23**	**$ (25)**	**$ 34**
Adjustments to Net Earnings	**$ 85**	**$ 45**	**$ 104**

(b) Structural optimization and other special charges represent the costs associated with:

	2024	2023	2022
Employee retention and workforce reductions	$ 23	$ 69	$ 74
Closure/transfer of manufacturing and other facilities	31	50	83
Product line exits	37	22	34
Termination of sales relationships	8	—	—
Other charges	39	29	104
Adjustments to Operating Income	**$ 138**	**$ 170**	**$ 295**
Adjustments to Other Income (Expense), Net	**$ 1**	**$ —**	**$ —**
Adjustments to Income Taxes	**$ 29**	**$ 38**	**$ 61**
Adjustments to Net Earnings	**$ 110**	**$ 132**	**$ 234**

(c) Goodwill and other impairments represent the costs associated with:

	2024	2023	2022
Goodwill impairments	$ 456	$ —	$ 216
Certain long-lived and intangible asset write-offs and impairments	466	26	8
Product line exits (e.g., long-lived asset and specifically-identified intangible asset write-offs)	55	10	46
Adjustments to Operating Income	**$ 977**	**$ 36**	**$ 270**
Adjustments to Income Taxes	**$ 125**	**$ 9**	**$ 5**
Adjustments to Net Earnings	**$ 852**	**$ 27**	**$ 265**

(d) Charges represent the costs specific to updating our quality system, product labeling, asset write-offs and product remanufacturing to comply with the medical device reporting regulations and other requirements of the new medical device regulations in the European Union.
(e) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain recall-related matters.
(f) Charges represent changes in our best estimate of the probable loss, or the minimum of the range of probable losses when a best estimate within a range is not known, to resolve certain regulatory or other legal matters and the amount of favorable awards from settlements.
(g) Benefits / (charges) represent the accounting impact of certain significant and discrete tax items, including:

	2024	2023	2022
Adjustments related to the transfer of certain intellectual properties between tax jurisdictions	$ (185)	$ (89)	$ (182)
Certain tax audit settlements	(1)	24	162
Reversal of deferred income tax on undistributed earnings of foreign subsidiaries	—	—	71
Deferred tax benefit on outside basis related to the anticipated sale of the Spinal Implants business	170	—	—
Other significant and discrete tax items	(12)	14	(80)
Adjustments to Income Taxes	**$ (28)**	**$ (51)**	**$ (9)**
Benefits for certain tax audit settlements	—	(9)	(45)
Other tax related adjustments	—	1	(30)
Adjustments to Other Income (Expense), Net	**$ —**	**$ (8)**	**$ (75)**
Adjustments to Net Earnings	**$ 28**	**$ 43**	**$ (66)**

FINANCIAL CONDITION AND LIQUIDITY

Net cash provided by (used in):	2024	2023	2022
Operating activities	$ 4,242	$ 3,711	$ 2,624
Investing activities	(3,000)	(962)	(2,924)
Financing activities	(525)	(1,594)	(749)
Effect of exchange rate changes	(36)	(28)	(51)
Change in cash and cash equivalents	**$ 681**	**$ 1,127**	**$ (1,100)**

We believe our financial condition continues to be of high quality, as evidenced by our ability to generate substantial cash from operations and to readily access capital markets at competitive rates despite the current macroeconomic environment. Operating cash flow provides the primary source of cash to fund operating needs and capital expenditures. Excess operating cash is used first to fund acquisitions to complement our portfolio of businesses. Other discretionary uses include dividends and share repurchases. We supplement operating cash flow with debt to fund our activities as necessary. Our overall cash position reflects our business results and a global cash management strategy that takes into account liquidity management, economic factors and tax considerations.

Operating Activities

Cash provided by operating activities was $4,242, $3,711 and $2,624 in 2024, 2023 and 2022. The increase in 2024 was primarily due to higher cash earnings partially offset by changes in working capital. The increase in 2023 from 2022 was primarily due to higher net earnings and increased collections on accounts receivable.

11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Y

Pharmacist Application

Non-Refundable $250 fee

132895

Rev (12/24/2024)

Section 1: Select how will you be obtaining your Nevada Pharmacist Registration

☐ **Examination**

☐ **Score Transfer** (Transfer your NAPLEX SCORE to Nevada within 89 days after taking your exam at https://nabp.pharmacy/ before completing this application.)

■ **Reciprocation** (Complete NABP's Electronic Licensure Transfer Program (e-LTP) application at https://nabp.pharmacy/ before completing this application.)

Are you submitting this application to RETAKE the NAPLEX and/or MPJE? ☐ Yes ■ No

Section 2: General Information

First: PAUL Middle: DOUGLAS Last: ARP

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Section 3: Employment Information

Pharmacy Name: INGLES PHARMACY #036 NV Pharmacy License # (if applicable):

Address: 5679 APPALACHIAN HWY

City: BLUE RIDGE State: GA Zip: 30513

Telephone: 706-632-3654 Email: [redacted]

Section 4: College of Pharmacy Information

School Name: University of Georgia College of Pharmacy

Address: 250 Green St

City: Athens State: GA Zip: 30602

Country/Territory/Province: USA

Graduation Date: 12/1987 Degree: ☐ PharmD ■ BS in Pharmacy ☐ Other

Section 5: ONLY COMPLETE this section if you are applying for a Nevada Pharmacist Registration by RECIPROCATION.

Original State of licensure/registration you are reciprocating from must be active and issued by exam (passing the NAPLEX and that state's MPJE).

State: GA License #: RPH015598 Date of Issuance: 03/09/1998 Expiry Date: 12/31/2026

Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.								
State	License/ Registration #	Issued Date	Expiry Date	License/Registration Status (check applicable box)				
				Active	Inactive	Expired	Revoked	Surrendered
TN	10203	07/31/1997	07/31/2001		✔	✔		

Section 7: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 9: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/25/2006	03/23/2007	GA	Canton	Cherokee

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2006-498	Georgia State Board of Pharmacy

Reason/Charge
Voluntary License Surrender

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Respondent	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

Investigative details and license reinstatement details are in the enclosed Consent Order issued by the Georgia Board of Pharmacy docketed March 23, 2007.

Original Signature (electronic, copies or stamps not accepted)

07/23/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

PAUL DOUGLAS ARP

Print Name

Paul Douglas Arp

Original Signature, no copies or stamps accepted

07/23/2025

Date

Board Use Only	Date Received: 7/31/25	Amount: $250cc
	NAPLEX:	MPJE:

BEFORE THE GEORGIA STATE BOARD OF PHARMACY
STATE OF GEORGIA

IN THE MATTER OF: *
*
Paul Douglas Arp, R.Ph. * Docket No.
License No. RPH015598 *
*
Respondent *

PROFESSIONAL LICENSING BOARDS
APR 21 2006
DOCKET NUMBER
2006-0498

VOLUNTARY SURRENDER

I, Paul Douglas Arp, holder of Pharmacist License No. RPH015598 to practice pharmacy in the State of Georgia pursuant to O.C.G.A. Ch. 26-4, as amended, hereby freely, knowingly, and voluntarily surrender said license to the Georgia State Board of Pharmacy.

I hereby acknowledge that this surrender shall have the same effect as a revocation of my license, and I knowingly forfeit and relinquish all right, title and privilege of practicing pharmacy in the State of Georgia, unless and until such time as my license may be reinstated, in the sole discretion of the Board.

I understand that I will be expected, in making any application or request for restoration of my license, to show my fitness to resume the practice of pharmacy.

I understand that I have a right to a hearing in this matter, and I hereby freely, knowingly and voluntarily waive such right. I also understand that should any request for reinstatement be entertained by the Board, the Board shall have access to the entire investigative file in this matter.

This surrender shall become effective immediately upon acceptance thereof by the Georgia State Board of Pharmacy. I understand that this document will be considered to be a public record evidencing disciplinary action taken against my license by the Georgia State Board of Pharmacy

with my consent.

Paul Douglas Arp, R.Ph.
Respondent

Sworn to and Subscribed

before me this 10th

day of February, 2006.

Julia Simmons
NOTARY PUBLIC
(Notary Seal Required)

My Commission expires:

JULIA SIMMONS NOTARY PUBLIC FULTON COUNTY EXPIRES GEORGIA OCT.12, 2008

ACCEPTANCE OF SURRENDER

The voluntary surrender of License No. RPH015598 is hereby accepted by the Georgia State Board of Pharmacy, this 18 day of April, 2006

GEORGIA STATE BOARD OF PHARMACY

by: Bill Prather
Bill Prather, R.Ph.
President

(Board Seal)

ATTEST: Mollie D. Fleeman
Mollie Fleeman
Division Director
Professional Licensing Boards

BEFORE THE GEORGIA STATE BOARD OF PHARMACY

IN THE MATTER OF	*	
	*	
PAUL DOUGLAS ARP	*	DOCKET NO. 2006-0498
License No. RPH015598	*	
	*	
Respondent.	*	

PROFESSIONAL LICENSING BOARDS
MAR 23 2007
DOCKET NUMBER
2006-0498

CONSENT ORDER FOR REINSTATEMENT

By agreement of the Georgia State Board of Pharmacy ("Board") and Paul Douglas Arp, Respondent, the following disposition of this matter is entered pursuant to the provisions of O.C.G.A. T. 43, Ch. 1, T. 26, Ch. 4, and T. 50, Ch. 13.

FINDINGS OF FACT

1.

Respondent was licensed to practice pharmacy in this state on March 9, 1988.

2.

On or about January 25, 2006, Respondent admitted to an agent of the Board that while employed at CVS Pharmacy, he filled approximately 118 fraudulent controlled substance prescriptions for his friends and himself over a four-year period.

3.

On or about April 21, 2006, Respondent voluntarily surrendered his license to practice pharmacy.

4.

On or about December 5, 2006, Respondent applied for reinstatement of his license to practice pharmacy.

5.

On or about January 10, 2007, Respondent met with the Board requesting reinstatement of his license to practice pharmacy.

6.

The Respondent waives any further findings of fact with respect to this matter.

CONCLUSIONS OF LAW

Under O.C.G.A. T. 26, Ch. 4, and T. 43, Ch. 1, the Georgia State Board of Pharmacy may impose conditions, as it deems appropriate on the reinstatement of Respondent's pharmacist license. Respondent waives any further conclusions of law with respect to this matter.

ORDER

The Board having considered the particular facts and circumstances of this case, it is hereby ordered, and the Respondent hereby agrees, as follows:

1.

Upon the effective date of this Order, the Respondent's license to practice pharmacy in the State of Georgia shall be reinstated but such license shall be placed on probation for a period of five (5) years and until discharged in accordance with paragraph (n), under the following terms and conditions of probation:

(a) **SUPERVISED PRACTICE.** Until further order of the Board as provided in Paragraph (b), **the Respondent license to practice pharmacy shall be limited such that the Respondent shall practice pharmacy only under the direct supervision of a pharmacist acceptable to the Board and only while said pharmacist is physically present to supervise said practice.** Respondent shall provide a copy of this Order to said supervisor, and shall cause said supervising pharmacist to submit monthly reports to the Board on Respondent's work performance and the number of hours actually worked. **If Respondent practices pharmacy when the supervisor is not physically present, then such action shall be grounds for revocation of Respondent's license.**

(b) **PETITION FOR LIFTING OF SUPERVISED PRACTICE.** When the Respondent has **worked** for at least **three (3) months with a minimum of 30 hours per week**, under the limitation set forth in Paragraph (a) above, the Respondent may petition the Board for termination of the limitation on practice provided in Paragraph (a) above. After the Board receives the petition and reviews the reports from Respondent's supervisor, the Board may request that the Respondent appear before the Board at a Board meeting prior to the lifting of the limitation. After the Board considers the petition and after the Respondent's appearance, if one is requested by the Board, the Board may enter an Order lifting the limitation on practice provided in Paragraph (a) above.

(c) **EMPLOYER REPORTS.** During the probationary period, Respondent shall provide a copy of this Consent Order to his employer and shall cause his employer to submit reports regarding his performance as a pharmacist. During the period when practice is limited as provided in Paragraph (a), the monthly reports shall satisfy the provisions of this Paragraph. If the limitation on practice is lifted in accordance with Paragraph (c), Respondent shall cause his employer to submit reports regarding his performance to the Board, by March 31st, June 30th, September 30th, and December 31st of each year, beginning with the first reporting period following the lifting of the limitation on practice.

(d) **PERPETUAL INVENTORY FOR CONTROLLED SUBSTANCES.** Respondent agrees that he shall maintain a perpetual running inventory of controlled substances, Schedules II through IV, in any pharmacy in which he works or is employed as a pharmacist. Said inventory must account for each and every dose of controlled substance received, stocked, dispensed or otherwise disposed of by the

pharmacy. Respondent shall keep said inventory available for inspection at any reasonable time requested by the Board or its agent.

(e) **NO PHARMACIST-IN-CHARGE.** During the probationary period, the Respondent shall not practice as the pharmacist-in-charge. The Respondent may not petition for modification of this provision of the Consent Order until at least one year from the effective date of this Order. After the Board receives the petition, the Board may request that Respondent appear before the Board at a Board meeting prior to the lifting of the limitation. After the Board considers the petition and after the Respondent's appearance, if one is requested by the Board, the Board may enter an Order lifting the limitation in this subsection.

(f) **PERSONAL REPORTS.** Respondent shall submit personal reports to the Board regarding Respondent's employment, by March 31st, June 30th, September 30th, and December 31st of each year, beginning with the first reporting period following the effective date of this Order. Such reports shall include any change of personal address or employment.

(g) **NO PHARMACY OWNERSHIP.** During the probationary period, Respondent shall not own a pharmacy. The Respondent may not petition for a modification of such limitation until at least one (1) year from the effective date of this Order. After the Board receives the petition, the Board may request that Respondent appear before the Board at a Board meeting prior to the lifting of the limitation. After the Board considers the petition and after the Respondent's appearance, if one is requested by the Board, the Board may deny the Petition or enter an Order lifting the limitation in

this paragraph. The limitation in this paragraph shall remain in effect until the Board enters an Order lifting the limitation or ending probation.

(h) **NAPLEX REVIEW COURSE.** Within the first two years of the probationary period, Respondent must take Pharmacy Examination Preparatory Course (NAPLEX review course). The Board must receive evidence of Respondent's compliance with this paragraph within the first two years of the probationary period identified in this Consent Order.

(i) **NOTIFICATION OF CHANGE**. The Respondent shall advise the Board in writing of any change in Respondent's residence and/or office address within ten (10) days of such change.

(j) **PRACTICE OUTSIDE GEORGIA.** In the event, the Respondent should practice outside the State of Georgia, the Respondent shall notify the Board in writing of such practice. **Periods of practice outside of Georgia will not apply to the reduction of the Respondent's probationary period.** The Respondent shall advise the Board of any change in Respondent's residence and/or office address.

(k) **ADDRESS FOR REPORTS.** All reports required under this Consent Order shall be sent to the **Georgia State Board of Pharmacy, to the attention of the Executive Director, 237 Coliseum Drive, Macon, Georgia 31217.**

(l) **VIOLATIONS AND ADDITIONAL SANCTIONS.** If the Respondent shall fail to abide by all State and Federal laws relating to drugs and/or regulating the practice of pharmacy, the Rules and Regulations of the Georgia State Board of Pharmacy, or the terms of this Consent Order and probation, or if it should appear from reports submitted to the Board that the Respondent is unable to practice pharmacy with reasonable skill

and safety, **the Respondent's license shall be subject to revocation, upon substantiation thereof, and the Board may determine that such revocation is permanent.**

(m) **PETITION FOR LIFTING OF PROBATION**. Within sixty (60) days of the scheduled date of termination of probation, Respondent may petition for termination of probation by certifying under oath before a notary public that the Respondent has complied with all conditions of probation and by providing documentation supporting discharge from probation.

(n) **TERMINATION/EXTENSION OF PROBATION**. The Georgia State Board of Pharmacy shall review and evaluate the practice of the Respondent prior to lifting the probation. At such time, the Board shall be authorized to restore all rights and privileges incident to the license of the Respondent, unless the Board has received information that the Respondent has not complied with the terms of probation or has otherwise failed to comply with the law and rules regulating her practice as a pharmacist. Should the Board determine that reasonable cause exists for maintaining Respondent's license on a probationary status, the Board shall notify Respondent of its intent to extend the probationary period, and Respondent may respond to such notification in writing or request an appearance before the Board or its representative as in a non-contested case. **In any event, this Consent Order shall remain in effect pending a final determination by the Board and notification that the probationary period has terminated.**

2.

This Consent Order shall be considered to be a public record of the Board and may be disseminated by the Board as disciplinary action.

3.

Approval of this Consent Order by the Georgia State Board of Pharmacy shall in no way be construed as condoning the Respondent's conduct and shall not be construed as a waiver of any of the lawful rights possessed by the Board. **This Consent Order shall not become effective until approved by the Board and docketed by the Division Director of the Professional Licensing Boards Division, Secretary of State.**

4.

Respondent acknowledges that he has read this Consent Order and that he understands its contents. Respondent understands that he has the right to an appearance in this matter, and Respondent freely, knowingly and voluntarily waives such right by entering into this Consent Order. Respondent understands that this Consent Order will not become effective until approved by the Georgia State Board of Pharmacy and docketed by the Division Director of the Professional Licensing Boards Division, Secretary of State. Respondent further understands and agrees that the Board shall have the authority to review the investigative file and all relevant evidence in considering this Consent Order. Respondent further understands that this Consent Order, once approved, shall constitute a public record that may be disseminated as a disciplinary action of the Board. If this Consent Order is not approved, it shall not constitute an admission against interest in this proceeding, or prejudice the ability of the Board to adjudicate this matter. Respondent consents to the terms and sanctions contained herein.

This 21st day of March, 2007.

GEORGIA STATE BOARD OF PHARMACY

BY: _____
JUDY L. GARDNER, PharmD.
President

ATTEST: _____
DONALD MUNDAY
Acting Division Director
Professional Licensing Boards Division

(BOARD SEAL)

CONSENTED TO:

_____
PAUL DOUGLAS ARP
Respondent

GA/C # 259270259

AS TO SIGNATURE OF PAUL DOUGLAS ARP
Sworn to and subscribed
before me this 16th day
of MAR, 2007.

_____
NOTARY PUBLIC
My commission expires: 4-18-2010

The Office of Secretary of State

Karen C. Handel
SECRETARY OF STATE

PROFESSIONAL LICENSING BOARDS
JUL 19 2007
DOCKET NUMBER
2006-0498

Donald W. Munday
DIRECTOR
PROFESSIONAL LICENSING BOARDS

July 13, 2007

Paul Douglas Arp
[redacted]

Dear Mr. Arp:

The Georgia State Board of Pharmacy reviewed your letter requesting that the Board terminate the supervision sanction of your Consent Order.

In their July 11, 2007 meeting, the Board voted to grant your request and terminate the supervision of your Consent Order the terms and conditions of 1(b) of your Consent Order from your Georgia Pharmacy License, Docket Number 2006-0498 and it is done so by this docketed letter effective July 2007.

If you have any questions, please contact the Executive Director, Lisa Durden or the Board's Administrative Assistant, Dianne W. Patterson at (478) 207-1606.

Sincerely,
GEORGIA STATE BOARD OF PHARMACY

Lisa Durden
Executive Director

LD/ddp

cc: Georgia Drugs and Narcotics Agency
Janet Wray, Attorney General Office

237 Coliseum Drive • Macon, Georgia 31217 • (478) 207-1300 • (478) 207-1363 FAX
www.sos.state.ga.us

The Office of Secretary of State

Karen C. Handel
SECRETARY OF STATE

Randall D. Vaughn
DIRECTOR
PROFESSIONAL LICENSING BOARDS

August 20, 2008

PROFESSIONAL LICENSING BOARDS
SEP 04 2008
DOCKET NUMBER
2006-0498

Paul Douglas Arp
[redacted]

Dear Mr. Arp:

The Georgia State Board of Pharmacy reviewed your letter requesting that the Board lift the No Pharmacist-In-Charge Terms from your Consent Order.

In their August 20, 2008 meeting, the Board voted to grant your request and lift the No Pharmacist In Charge terms noted in the Consent Order from your Georgia Pharmacist License, docket number 2006-0498 and it is done so by this docketed letter effective August 2008.

If you have any questions, please contact the Board's Executive Director, Anita O. Martin, or the Administrative Assistant, Dianne W. Patterson, at (478) 207-1606.

Sincerely,

GEORGIA STATE BOARD OF PHARMACY

AOMartin

Anita O. Martin
Executive Director

AOM/ddp

cc: Georgia Drugs and Narcotics Agency
Janet Wray, Attorney General Office

237 Coliseum Drive • Macon, Georgia 31217 • (478) 207-2440 • (866) 888-1178 FAX
www.sos.state.ga.us

PROFESSIONAL LICENSING BOARDS

JAN 22 2010

DOCKET NUMBER
2006-0498

The Office of Secretary of State

Brian Kemp
SECRETARY OF STATE

Randall D. Vaughn
DIVISION DIRECTOR
PROFESSIONAL LICENSING BOARDS

January 19, 2010

Paul Douglas Arp
[redacted]

Dear Mr. Arp:

At the January 13, 2010 meeting of the Georgia State Board of Pharmacy the board voted to waive the NAPLEX review course from your Public Consent Order Docket 2006-0498. This docketed letter will serve as official notification of that action.

If you have any questions, please do not hesitate to contact our office at (478) 207-2440.

Sincerely,

GEORGIA STATE BOARD OF PHARMACY

aOMartin

Anita O. Martin
Executive Director

PROFESSIONAL LICENSING BOARDS

NOV 20 2012

DOCKET NUMBER
2006-0498

The Office of Secretary of State

November 16, 2012

Paul Douglas Arp
[redacted]

Re: RPH015598
Public Consent Order 2006-0498

Dear Paul Arp:

At its meeting on May 9, 2012, the Georgia State Board of Pharmacy considered your request to have the probation restriction lifted from your Public Consent Order, Docket Number 2006-0498. The Board voted to lift the probation restriction from your Public Consent Order. This restriction is lifted upon docketing of this letter.

If you have any further questions, please contact the Board again.

Sincerely,

Georgia Board of Pharmacy

237 Coliseum Drive • Macon, Georgia 31217 • (478) 207-2440 •
www.sos.ga.gov

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application

Non-Refundable $50 fee

Rev (12/17/2024)

Section 1: General Information

First: Crystal Middle: Irene Last: Lara

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: M (F) X

Mailing Address: [redacted]

City: [redacted] State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)

Program/School Name: CVS pharmacy

Address: 2878 Vista Blvd

City: Sparks State: NV Zip: 89434

Name of Program Director:

Section 3: Employment Information

Pharmacy Name: CVS pharmacy License #: PT28740

Address: 2878 Vista Blvd.

City: Sparks State: NV Zip: 89502

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

High School Name: Rise Academy Graduation Date OR Date GED obtained (mm/yy): 01/2022

Address: 2886 Sutro Building B

City: Reno State: NV Zip: 89512

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: WARNING **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**	**Initials** CL	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	X	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2011		~~X~~ Ca	Ventura	L.A.
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

This happend over 10 years ago I completed a drug and alcohol class and do. I do not have any access to the documentations anymore.

Original Signature (electronic, copies or stamps not accepted)

10/14/25
Date

Section 8: You MUST submit the documents below with your application base on your qualifications as a PT.	
Select your qualification as a PT (please check a box).	**Required documents to be submitted with your application.**
The successful completion of an ASHP-approved PT school or training program	a. Provide a copy of the certification of completion of the program.
Active practice in good standing in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by **a signed affidavit** by the managing pharmacist of the pharmacy.	a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing. b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).
The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy.	a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application).
The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs.	a. Provide a copy of the certification of completion of the program.

Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371

In addition to the requirements in section 7, submit fingerprints for a background check by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371%20updated%2012.16.24(1).pdf.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Crystal Lara
Print Name

Crystal Lara
Original Signature, no copies or stamps accepted

10/14/25
Date

Board Use Only	Date Received: _____	Amount: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Nevada Managing Pharmacist Certification of Training Hours for Pharmaceutical Technician in Training (PTT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

Section 1: Certification of PTT (NAC 639.242) MUST BE COMPLETED BY THE PHARMACY MANAGER

Name of PTT: Crystal Lara
PTT License #: PTZ8740

Pharmacy Manager Name: Balraj Buttar
Pharmacy Manager License #: 14834

Name of Pharmacy: CVS pharmacy
Pharmacy License #: PH01833

Pharmacy Address: 2878 Vista BLVD

City: Sparks NV. 89434
State: NV Zip: 89436

Time period PTT employed (mm/yy-mm/yy): 06/2023 to present

I certify to the Board that the above-named PTT has successfully completed 1500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

Pick up, drop off, input, resolution, ~~ansers~~ answering phone calls, ordering, inventory management, production, pulling expired and sending back.

Do you certify that the PTT is competent to perform the duties of a pharmaceutical technician? ☑Yes ☐No (If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

BALRAJ BUTTAR

Print Name (First, Last)

Balraj

Original Signature of Managing Pharmacist, no copies or stamps accepted

10-11-2025

Date

Board Use Only	Date Received: 10/14/25

13

13A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: FISBAY Middle: HAIDER Last: ALI

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 20660 Specialty: Psychiatry

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Hope LLC

Practice Address: 500 N Rainbow Blvd Suite #: 313

City: Las Vegas State: NV Zip: 89107

Telephone: (702) - 805-3059 Fax: _____ Email: hopehopellc@gmail.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✓	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

I have attached explanation as well as documentation.

[signature] 12/9/25

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HISBAY ALI — Print Name (First, Last)

12/9/25 — Date

Original Signature (electronic, copies or stamps not accepted)

12/9/25 — Date

Board Use Only: Date Processed: 12/11/25 Amount: $200 CK 6142401502

Individual Details

Name : Ali Hisbay Haider

Individual ID : 110874

DOB : [redacted]

License# : CS31898

Original Issue Date : 07/01/2021

Mailing Address : [redacted]

Practice Phone : (702) 202-0099

Home Phone : [redacted]

Cell Phone

Email Address : [redacted]

License Details

Controlled Substance - 11/05/2024 - 10/31/2026 - Suspended pursuant to NRS 639.2107

Controlled Substance - 11/01/2022 - 10/31/2024 - Renewed

Controlled Substance - 07/01/2021 - 10/31/2022 - Renewed

U. S. Department of Justice - Drug Enforcement Administration

DEA USE ONLY

File No.

SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list I chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

NAME OF REGISTRANT *(Print)*	ADDRESS OF REGISTRANT
HISBAN ALI, M.D.	[redacted]
DEA REGISTRATION NO [redacted]	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL	DATE
[signature]	11/7/24

WITNESSES TO REGISTRANT'S SIGNATURE

NAME AND DATE	TITLE
ESTEVAN SANCHEZ 11/7/24 [signature]	DIVERSION INVESTIGATOR
NAME AND DATE	TITLE
[signature] 11/7/24	DIVERSION INVESTIGATOR

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).
PURPOSE: Permit surrender for cause of DEA Certificate of Registration.
ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided.

December 9th, 2025

Attention: Nevada State Board of pharmacy,

I am writing this explanation, which should cover all relevant material in the hopes of obtaining a new controlled substance license as I had surrendered my DEA license last year, and the controlled substance license had also been revoked as a result. I had a controlled substance license and a DEA license when I first moved here in 2021 and had it active until November 2024 during which time the license had been revoked as a cascade effect of the medical board suspending my license prior to having a hearing, after which a settlement was reached on June 6 of 2025.

Section 5:

1. I do not believe I have any actual diagnosis for substance abuse, nor have I been treated for any mental health condition. I did get arrested for a misdemeanor DUI in April of 2024 in Las Vegas, the case has since been settled with the one-year probation until October 2025. I did require an intoxalock breathalyzer device in my car, after my driver's license was suspended, but that has been successfully completed, and my driver's license is now unrestricted and active. Although no formal diagnosis of alcohol use disorder has been rendered, I have been free from drinking alcohol for 14 months now and voluntarily use sober linked device, which is monitored by the professional health monitoring program supervisor (Mark Chase) for Nevada state. I underwent substance abuse evaluation (routine for DUI by the medical board) by Mark Chase and the medical board accepted his clearance with no issues reported by him affecting my ability to perform the essential functions of my license. I have checked "no" to any impairment to carry out the duties of my license because of the PHP and evaluation by a psychiatrist both of which cleared me to return to practice. I have never had any issues with substance use or abuse that affected work and have never had an issue while working. However, I had enrolled voluntarily enrolled in PHP following the DUI and to satisfy any requirements for Nevada state to ensure compliance with the Nevada State medical Board and will remain in the PHP for 5 years.

2. I was charged and convicted of two DUI in New York in 2015. I was on probation for three years and completed that in 2019 successfully. Here in Nevada, I was arrested in December 2022, due to a domestic violence argument, where my ex-girlfriend had called the police for alleged domestic violence. However, no charges, were accepted by the police as they found them

to be false and the charges were in fact denied by the police so it never to court. I have explained this to the medical board as well. There is no court documentation or otherwise as charges were not accepted but I want to disclose encounter. I have already disclosed the 2 DUI arrests in NY from 10 years ago and the resulting documentation was provided to the Board of Pharmacy almost 5 years ago. There is no change in that status, but I can provide a discharge from probation letter from the PO back in 2019. In July 2025, I was in a four-car accident with no serious injuries. I had been arrested at the scene of the crime because of not having the intoxalock in the new car that I had. However, the record had not been updated at the DMV, that was that clarified and the charges were dropped as I had already fulfilled that the requirements for that and it was an updating error on the part of the DMV. Included in this is a letter from the court to my lawyer for the DUI as well as the second arrest in the summer of this year, which was dropped due to a technicality error on the part of the DMV. The charges were dropped to a traffic misdemeanor of not keeping a safe distance while driving. I have let the medical board know about this as well and they were satisfied with the explanation and resultant disposition.

3. I have been the subject of the medical board, taking administrative action due to a former patient reporting an inappropriate relationship as well as failure to report the 2024 DUI arrest within 30 days as required by the board. I also admitted to failure to maintain proper records as alleged in the complaint, although the case is more complicated because I had been locked out of the medical records from the old practice that I had been in and was unable to complete some of the records, but I had admitted and accepted the charge as part of the agreement. The settlement agreement was reached in June 2025. I will attach a copy of the agreement from the Nevada state board of medical examiners. This included paying a fine and legal cost as well as revocation of the license, which was lifted on December 8 of 2025, and status of my license is currently on probation for five years. The terms of this probation which are included in the agreement have been attached below include being monitored by the professional health monitoring program, as well as having a female chaperone for all female patients. This also include included completing a PROBE course on ethics which I completed in September and submitted to the board, as well as 20 hours of continuing medical education which include included 10 hours of ethics as well as five hours of substance use treatment and five hours of proper prescribing practices. These have all been submitted to the medical board and they have accepted it resulting in my license suspension being lifted and my license is now currently in the probationary stage. I had an active license in NY from 2017 till 2021 but have not kept it active and when I

was approached by NY to explain the events leading to the board hearing in Nevada, they were satisfied with notarized document from me saying that I was not practicing in NYS nor do I have any intention to.

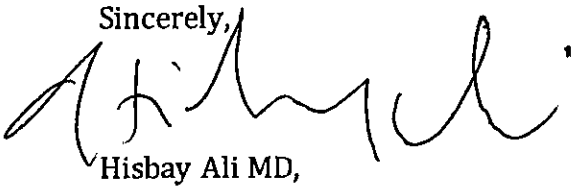
I would like to provide a little more explanation regarding the primary allegation of coercing a patient into a personal relationship. The case is complicated, and I accepted the charge and subsequent measures needed in my practice, to restore my license. The complainant, i.e. former patient had been hired by a former Clinic owner whom I had worked for. This owner and physician had his Medicaid and Medicare privileges revoked for fraudulent billing, and unbeknownst to me at the time had attempted to use my license for that purpose (This had been reported and documented by the board in 2022, and this individual did face sanctions by Medicaid eventually. He also tried to set up a video camera in my office and had hired a woman who had as I found out later already tried to blackmail and or file civil lawsuit against two other previous doctors for similar accusations. Patient had asked to engage in intimate and inappropriate activities in the office, which I declined. I had then terminated care with this patient and transferred patient to another provider, but patient had not followed up. In addition, I had been locked out of the electronic health records by the owner of the clinic who had attempted to use my medical license for unauthorized billing. I admit the former patient then invited me back to her apartment a few months later. And had set up a video camera and recorded myself and her illegally using a video camera without my consent. She then reported this encounter to the medical board as well as filing a civil lawsuit after she had tried to blackmail me. She also made a false allegation that I inappropriately prescribed medications to her, but this was found to be false during the investigation. I admit that I made a gross misjudgment in having any kind of relationship outside of a professional psychiatrist and patient relationship. The patient had come to see me three times in my clinic between November and January of 2021. The civil lawsuit did not end up in court and was settled out of court with no admission of guilt and no judgment. However, I admit that I made a poor decision to engage with a former patient in any capacity, and I accept responsibility for that. As a result of the hearing with the medical board, I did admit to the Charge and agreed to have a female chaperone for the next five years present for all female patients. Currently, I have a clinical practice that is waiting for me to return to work that has two female chaperones that are registered with the medical board, and they have accepted that as a solution. I also completed a PROBE ethics course. And 10 hours of CME for ethics as well as five hours for substance use treatment and five hours for proper prescribing practices. I also admitted to failure to keep appropriate medical records, although as explained above, I had been locked out of the medical records by the owner of the clinic, but I admitted to that as part of the agreement to get my medical license active again eventually. As a result, I have agreed to have a third-party chart review company evaluate 10 to 50 percent of my charts every

quarter. I believe one of the charges had also included failure to check PMP regularly so as part of the settlement agreement I have agreed to have PMP for controlled substances checked every visit and documented and this will be checked by a third part medical records evaluator.

4. My license has not been subject to any discipline for violation of pharmacy or drug laws other than my controlled substance license being suspended by the Nevada State Board of Pharmacy in November of 2024 due to the suspension of my medical license. I also surrendered my DEA license voluntarily after the medical license suspension and will be looking to file for a new number if approved.

Along with the application, I will send in a copy for the explanation of the arrest in New York from 10 years ago, which I believe the board may already possess. I will also send a copy of the settlement agreement with the medical board. I do not have any final disposition for the DUI arrest from 2024 here in Nevada since I am currently on probation with a check in with the court in March 2026 and the final check-in in October 2026, at which point my probation will be completed if successful. I expressed regret in the matter, and I hope that the Board will the steps that I have taken, and which have been approved by the medical board to be satisfactory. If there are any questions at the Board may have for further clarification, feel contact me at [redacted] or you can call me at [redacted] As someone who has struggled with alcohol use and is currently in treatment and being monitored, I understand and have empathy for people who may be affected by this illness, and if given the privilege to obtain a controlled substance license as previously obtained, I promise to practice safe and appropriate prescriptions of controlled substances and to use them judiciously and help the community address substance abuse, and misuse issues to the best of my knowledge and experience, including personal experience. Previously, I had a DEA license, as well as having the X waiver and ability to prescribe Suboxone. I had surrendered my DEA license last year with the suspension of my medical license, and I spoke with the investigator who had said that if the control substance license is successful, then he can assist me in obtaining a new DEA license as well. I appreciate the Nevada State Board of pharmacies consideration for a controlled substance license.

Sincerely,



Hisbay Ali MD,

Board certifications:

American board of psychiatry and Neurology.

American Board of Consultation – liaison psychiatry

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BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **HISBAY HAIDER ALI, M.D.,** **Respondent.**	**Case Nos. 24-53587-1** **24-53587-2** **24-53587-3**

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, Senior Deputy General Counsel for the Board and attorney for the IC, and Hisbay Haider Ali, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Richard Schonfeld, Esq., of the law firm of Chesnoff & Schonfeld, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in suspended status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on December 31, 2020 (License No. 20660).

2. On March 18, 2024, in Case No. 24-53587-1, the IC filed a formal Complaint (Complaint I) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges one (1) violation of NRS 630.301(4), Malpractice (Count I); one (1) violation of NRS 630.304(5), Influencing a Patient to Engage in Sexual Activity (Count II); one (1) violation of NRS 630.301(5), Engaging in Sexual Activity with a Patient (Count III); one (1)

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

violation of NRS 630.3062(1)(a), Failure to Maintain Complete Medical Records (Count IV); one (1) violation of NRS 630.306(1)(p), Unsafe or Unprofessional Conduct (Count V); one (1) violation of NRS 630.301(9), Disreputable Conduct (Count VI); one (1) violation of NRS 630.304(7), Terminating Medical Care without Adequate Notice to a Patient (Count VII); and one (1) violation of NRS 630.301(7), Violation of Patient Trust and Exploitation of the Physician and Patient Relationship for Financial or Personal Gain (Count VIII).

3. On April 24, 2024, in Case No. 24-53587-2, the IC filed a formal Complaint (Complaint II) charging Respondent with violating the Medical Practice Act. Specifically, Complaint II alleges one (1) violation of NRS 630.301(4), Malpractice (Count I); one (1) violation of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Count II); and one (1) violation of NRS 630.306(1)(b)(3), Violation of the Statutes and Regulations of the Nevada State Board of Pharmacy (Count III).

4. On October 11, 2024, in Case No. 24-53587-3, the IC filed a formal Complaint (Complaint III) charging Respondent with violating the Medical Practice Act. Specifically, Complaint III alleges one (1) violation of NRS 630.304(1), Dishonesty in Renewing a License, (Count I); two (2) violations of NRS 630.306(1)(I), Failure to Report Criminal Action or Conviction (Count II-III); and one (1) count of violation of NRS 630.301(9), Disreputable Conduct (Count IV). Complaints I, II, and III are herein referred to collectively as the "Complaints." By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

5. Respondent was properly served with a copy of the Complaints, has reviewed and understands the Complaints, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

6. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaints. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is

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contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaints, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

7. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

8. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaints, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaints has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this

matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaints filed in this matter, including defense of the Complaints, adjudication of the allegations set forth in the Complaints, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaints as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaints remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges Respondent is not admitting that the IC's claims/counts as alleged in the Complaints have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaints, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

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5. **Consent to Entry of Order**. In order to resolve the Complaints pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Count II, NRS 630.304(5), Influencing a Patient to Engage in Sexual Activity; Count III, NRS 630.301(5), Engaging in Sexual Activity with a Patient; and Count VII, NRS 630.304(7), Terminating Medical Care without Adequate Notice to a Patient as alleged in Complaint I.

b. Respondent admits to Count I, NRS 630.301(4) Malpractice, and Count II, NRS 630.3062(1)(a), Failure to Maintain Proper Records as alleged in Complaint II.

c. Respondent admits to Counts II and III, NRS 630.306(1)(I), Failure to Report Criminal Action or Conviction as alleged in Complaint III.

d. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matters in the amount of sixty-two thousand eight hundred eleven dollars and seventy-six cents ($62,811.76). Respondent shall pay the aforementioned costs and expenses by way of eighteen (18) payments, the first six (6) payments shall be in the amount of one thousand dollars ($1,000), the subsequent eleven (11) payments shall be in the amount of four thousand seven hundred thirty-four dollars and thirty-one cents ($4,734.31) and the final payment which shall be in the amount of four thousand seven hundred thirty-four dollars and thirty-five cents ($4,734.35). The first of six (6) payments in the amount of one thousand dollars ($1,000) is due on or before July 15, 2025, the second payment is due on or before August 15, 2025, the third payment is due on or before September 15, 2025, the fourth payment is due on or before October 15, 2025, the fifth payment is due on or before November 15, 2025, and the sixth payment is due on or before December 15, 2025. The first of twelve (12) payments in the amount of four thousand seven hundred thirty-four dollars and thirty-one cents ($4,734.31) is due on or before January 15, 2026, the second payment is due on or before February 15, 2026, the third payment is due on or before March 15, 2026, the fourth payment is due on or before April 15, 2026, the fifth payment is due on or before May 15, 2026, the sixth

payment is due on or before June 15, 2026, the seventh payment is due on or before July 15, 2026, the eighth payment is due on or before August 15, 2026, the ninth payment is due on or before September 15, 2026, the tenth payment is due on or before October 15, 2026, the eleventh payment is due on or before November 15, 2026, and the final payment is due on or before December 15, 2026 in the amount of four thousand seven hundred thirty-four dollars and thirty-five cents ($4,734.35). The total amount of costs and expenses paid to complete the agreement is sixty-two thousand eight hundred eleven dollars and seventy-six cents ($62,811.76). The costs and expenses as well as the payment plan are subject to the Board's acceptance, adoption, and approval of this Agreement.

e. Respondent shall pay a fine of twenty thousand dollars ($20,000) in eleven (11) equal payments of one thousand six hundred and sixty-six dollars and sixty-six cents ($1,666.66) and a twelfth final payment which shall be in the amount of one thousand six hundred sixty-six dollars and seventy-four cents ($1,666.74). The first is due on or before January 15, 2026, the second payment is due on or before February 15, 2026, the third payment is due on or before March 15, 2026, the fourth payment is due on or before April 15, 2026, the fifth payment is due on or before May 15, 2026, the sixth payment is due on or before June 15, 2026, the seventh payment is due on or before July 15, 2026, the eighth payment is due on or before August 15, 2026, the ninth payment is due on or before September 15, 2026, the tenth payment is due on or before October 15, 2026, the eleventh payment is due on or before November 15, 2026, and the final payment is due on or before December 15, 2026 in the amount of one thousand six hundred sixty-six dollars and seventy-four cents. The payment plan is subject to the Board's acceptance, adoption, and approval of this Agreement

f. Respondent's license shall remain in a suspended status for six (6) months following the Board's acceptance and adoption of the Global Settlement Agreement (Suspension Period). The lifting of the Respondent's suspension shall be contingent upon the following terms:

i. Respondent shall complete the Professional Problem-Based Ethics Program (PROBE) offered by the Center for Personalized Education for Physicians (CPEP) and pass without conditions, the cost of which shall be borne by the Respondent;

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ii. Respondent shall be evaluated by a properly certified substance use disorder/detoxification technician pursuant to NRS chapter 458 and undergo a substance use disorder evaluation and follow the recommendations of the technician, the cost of which shall be borne by the Respondent;

iii. Respondent shall undergo and pass a fitness for duty evaluation to assess his competence and ability to practice medicine safely and ethically, the cost of which shall be borne by the Respondent; and

iv. Respondent shall perform twenty (20) hours of Continued Medical Education (CME), with ten (10) hours related to medical ethics, five (5) hours related to proper prescribing practices, and five (5) hours related to alcohol and drug abuse. These twenty (20) hours of CME are in addition to the CME requirements that are regularly imposed upon Respondent as a condition of licensure in the State of Nevada pursuant to NAC 630.153(1), and shall be approved by the Board prior to their completion.

g. Respondent must always be accompanied by a chaperone during any and all interactions with female patients. A list of chaperones used by Respondent must be submitted to the Board before Respondent begins practicing medicine. Further, Respondent agrees that the Board may request records from his practice, or any practice he is associated with, to ensure compliance with the chaperone requirement. This condition shall not be petitioned for removal by Respondent for a minimum of three (3) years following the Board's acceptance, adoption, and approval of this Agreement.

h. Respondent's license shall be revoked for five (5) years from the date of the Board's acceptance, adoption, and approval of this agreement. The revocation shall be stayed, and Respondent shall be subject to a term of probation for five (5) years from the date of the Board's acceptance, adoption and approval of this Agreement. If Respondent fails to comply with the terms and conditions of this probation or commits a new violation of the Medical Practice Act during the probationary period, the stay of revocation will be immediately lifted, and the revocation shall be in full effect. Respondent shall be subject to the following probationary terms and conditions:

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i. Respondent must be monitored by Strategic Management Services or other monitoring company approved in the reasonable judgement of the Board. The monitoring company shall provide quarterly reports to the Board regarding its review of Respondent's charts and patient records. Strategic Management Services, or other monitoring company, shall review 10% of Respondent's patient charts each quarter, not to exceed fifty (50) charts per quarter and provide a report to the Board. Strategic Management Services, or other monitoring company, will be reviewing all aspects of these patient charts, including legibility, completeness of records, verification of the presence of a chaperone for visits with female patients, and compliance with Nevada law regarding prescribing controlled substances, such as proof of regular Nevada State Pharmacy Board Prescription Monitoring Program report queries for patients;

ii. Respondent shall pay all costs associated with the monitoring of him and/or his practice conducted by Strategic Management Services or other monitoring company approved in the reasonable judgement of the Board; and

iii. Respondent shall obtain drug and alcohol counseling and remain in a drug and alcohol recovery program on at least a monthly basis for the duration of the probationary period. Respondent shall provide the name of his chosen therapist to the Board, and agrees to the therapist providing quarterly reports directly to the Board regarding his compliance with this provision. Respondent shall provide the Board any changes of contact information for the required drug and alcohol counseling immediately upon his learning of a change or as soon thereafter as possible.

i. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

j. Respondent shall receive a Public Letter of Reprimand.

k. The remaining counts of the Complaints, and any other claims arising from the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents

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are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of the Complaints. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaints and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaints shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and

effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering the Complaints and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a). Additionally, failure to pay any fines, costs, expenses or fees owed to the Board pursuant to this Agreement will result in immediate suspension pending resolution of any payment delinquency, unless within ten (10) calendar days of the payment due date, Respondent notifies the Board in writing of the inability to comply with the payment terms and requests to appear before the Board

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at the next regularly scheduled Board meeting to request a modification to the payment(s) ordered in this Agreement.

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this _____ day of May, 2025.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By:_____
IAN J. CUMINGS
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

DATED this _____ day of May, 2025.

CHESNOFF & SCHONFELD

By:_____
RICHARD SCHONFELD, ESQ.
520 S. Fourth Street
Las Vegas, NV 89101
Tel: (702) 384-5563
Email: rschonfeld@cslawoffice.net
Attorney for Respondent

DATED this _____ day of May, 2025.

By: _____
HISBAY HAIDER ALI, M.D.,
Nevada License No. 20660
Respondent

copy of Settlement Agreement.

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LAW OFFICE
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EMAIL: dbrown@brownlawlv.com

September 3, 2025

Hisbay Ali
[redacted]

Re: City of Las Vegas vs. Hisbay Ali
Case no. 24-016327

Dear Mr. Ali,

As you know, David T. Brown, Esq. appeared in Las Vegas Municipal Court in reference to the above-captioned matter. At said time, you stipulated to the violation against you. Accordingly, the Court has ordered you to complete the following:

1. Pay a total fine amount of ($1,140.00) – increased from ($910.00);
2. Complete 24 Hours of Community Service;
3. Complete Repeat Offender Traffic School;
4. Refrain from the use of alcohol, drugs, and marijuana; and
5. Extend your Stay Out of Trouble Requirement;

A **Status Check** regarding the completion of the above requirements has been scheduled for **March 3, 2026 at 8:30 a.m.** in Las Vegas Municipal Court, Department 1, which is located at 100 E. Clark Ave, Las Vegas, NV 89101. **Your appearance at said hearing is required and you will be tested at this appearance.**

Thank you for your cooperation in this regard. If you should have any further questions or concerns, please do not hesitate to contact the undersigned.

Sincerely yours,

BROWN, BROWN & PREMSRIRUT

Alexis L. Budner
Legal Assistant to
David T. Brown, Esq.

LAW OFFICE
Brown, Brown & Premsrirut
AN ASSOCIATION OF PROFESSIONAL CORPORATIONS
JAY H. BROWN
DAVID T. BROWN
PUOY K. PREMSRIRUT
820 SOUTH FOURTH STREET
LAS VEGAS, NEVADA 89101-6520
TELEPHONE (702) 384-5563
FACSIMILE (702) 385-1023
EMAIL: dbrown@brownlawlv.com

June 25, 2025

Hisbay Ali
[redacted]

Re: City of Las Vegas vs. Hisbay Ali
Case no. 24-016327

Dear Mr. Ali,

As you know, David T. Brown, Esq. appeared in Las Vegas Municipal Court in reference to the above-captioned matter. At said time, a No Contest plea to the charge of Driving Under the Influence. Accordingly, the Court has ordered you to complete the following:

1. Pay a fine in the amount of Nine Hundred and Ten Dollar ($910.00);
2. Pay the required fees for, attend and complete a Victim Impact Panel;
3. Pay the required fees for, attend and complete DUI School;
4. Refrain from the use of alcohol, drugs, and marijuana;
5. Stay out of trouble until your case is closed;
6. Receive a 179 day suspended sentence you may be required to serve in the event you do not complete these requirements successfully.

A **Status Check** regarding the completion of the above requirements has been scheduled for **June 26, 2026 at 8:30 a.m.** in Las Vegas Municipal Court, Department 1, which is located at 100 E. Clark Ave, Las Vegas, NV 89101. **Your appearance at said hearing will not be mandatory if you forward all proof to this office by June 12, 2026.**

Thank you for your cooperation in this regard. If you should have any further questions or concerns, please do not hesitate to contact the undersigned.

Sincerely yours,

BROWN, BROWN & PREMSRIRUT

Alexis L. Budner
Legal Assistant to
David T. Brown, Esq.

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

November 4, 2024

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO: [redacted]

Hisbay Haider Ali, M.D.
[redacted]

Re: Suspension of Certificate of Registration No. CS31898 (Case No. 24-444-CS-S)

Dear Dr. Ali:

The Nevada State Board of Pharmacy (Board) has received notice that the Nevada State Board of Medical Examiners summarily suspended your license to practice medicine, effective October 11, 2024. Pursuant to NRS 639.2107, the suspension of your medical license by the Board of Medical Examiners operates as an immediate suspension of your certificate of registration to prescribe controlled substances.

Accordingly, you are **not** authorized to prescribe any controlled substances in the state of Nevada. Additionally, since you are no longer authorized to access the Nevada Prescription Monitoring Program (PMP) database, your access to the database is terminated effective immediately.

You may request a hearing before the Board to contest the above finding (i.e., that the Nevada State Board of Medical Examiners summarily suspended your license to practice medicine) by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the foregoing does not preclude a formal investigation or the filing of administrative disciplinary charges pursuant to NRS 453.241. If you have any questions, please do not hesitate to contact me at 775-850-1440, ext. 124, or via email at zunino@pharmacy.nv.gov.

Sincerely,

Gregory L. Zunino
Senior General Counsel
Nevada State Board of Pharmacy

LAURA CURRAN
COUNTY EXECUTIVE

JOHN PLACKIS
PROBATION DIRECTOR

NASSAU COUNTY PROBATION DEPARTMENT

400 COUNTY SEAT DRIVE
MINEOLA, NY 11501-4823

7-23-2019

Hisbay Ali
[redacted]

Re: NY-394228051

Dear Mr. Ali:

Please be advised you have been discharged from probation supervision effective 7-06-2019. As you are no longer under probation supervision the condition of probation requiring you to install and maintain an Ignition Interlock device in any vehicle registered to or driven by you is no longer in effect. You are advised that being released from probation will have no effect on your DMV restriction and you may not drive without an ignition interlock device until you clear the restriction with DMV.

We wish you success in your future endeavors.

Sincerely,

Institution	Program Type	Specialty Type	Start Date	End Date
Nassau University Medical Center / East Meadow, NY	Internship	Psychiatry	Jul-01-2010	Jun-30-2011
Nassau University Medical Center / East Meadow, NY	Residency	Psychiatry	Jul-01-2011	Jun-30-2014
Nassau University Medical Center / East Meadow, NY	Fellowship	Psychosomatic Medicine	Jul-01-2014	Jun-30-2015

Board Actions

Summary	Attachments
FORMAL COMPLAINT Case No. 24-53587-1 March 18, 2024 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Hisbay Haider Ali, M.D. alleging eight (8) violations of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(4) Malpractice. Count II: Alleges a violation of NRS 630.304(5) Influencing a Patient to Engage in Sexual Activity. Count III: Alleges a violation of NRS 630.301(5) Engaging in Sexual Activity with a Patient. Count IV: Alleges a violation of NRS 630.3062(1)(a) Failure to Maintain Complete Medical Records. Count V: Alleges a violation of NRS 630.306(1)(p) Unsafe or Unprofessional Conduct. Count VI: Alleges a violation of NRS 630.301(9) Disreputable Conduct. Count VII: Alleges a violation of NRS 630.304(7) Terminating Medical Care without Adequate Notice to a Patient. Count VIII: Alleges a violation of NRS 630.301(7) Violation of Patient Trust and Exploitation of Physician and Patient Relationship for Financial or Personal Gain. Complaint: six (6) pages.	Complaint 24-53587-1.pdf (/rest/public/data/downloadannotation/index.php?id=660aeda62f4f44f55fbccc27&entity=$2y$10$YNX7nVDKxA049M3.qlUgB.GGuRGNeLFPA6E/VOamonoN7NU7m/qTK)

Hisbay Haider ALI

License Number:
20660

License Type:
Medical Doctor

License Status:
Expired

Initial License Date:
Dec-31-2020

Expiration Date:
Jun-30-2025

Public Address:
[redacted]

Public City:
Las Vegas

Public State:
Nevada

Public ZIP Code:
89134

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Psychiatry
Child Psychiatry

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
St George's Univ. SOM / Grenada, WEST INDIES	Medical Doctor Degree	N/A	Dec-31-2008

Postgraduate Training

Summary	Attachments
FORMAL COMPLAINT Case No. 24-53587-2 April 24, 2024 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Hisbay Haider Ali, M.D. alleging three (3) violations of Nevada Revised Statutes (NRS) Chapter 630. Count I: Alleges a violation of NRS 630.301(4) Malpractice. Count II: Alleges a violation of NRS 630.3062(1)(a) Failure to Maintain Complete Medical Records. Count III: Alleges a violation of NRS 630.306(1)(b)(3) Violation of Statutes and Regulations of the Nevada State Board of Pharmacy. Complaint: six (6) pages.	Complaint 24-53587-2.pdf (/rest/public/data/downloadannotation/index.php?id=662fc89a04f43602b3a6363a&entity=$2y$10$RMF0ecpJp1YQvptW/TK5JOPYJwJDvLbY.ugJgMevR5DkhR8ApXFxa)
FORMAL COMPLAINT Case No. 24-53587-3 October 11, 2024 The Investigative Committee of the Nevada State Board of Medical Examiners filed a formal Complaint against Hisbay Haider Ali, M.D., alleging four (4) violations of the Nevada Medical Practice Act, including: one (1) violation of NRS 630.304(1), Dishonesty In Renewing a License (Count I); two (2) violations of NRS 630.306(1)(l), Failure to Report Criminal Action or Conviction (Counts II and III); one (1) violation of NRS 630.301(9), Disreputable Conduct (Count IV). Complaint: six (6) pages.	Complaint - 24-53587-3.pdf (/rest/public/data/downloadannotation/index.php?id=67097fc24d8f5021449269b0&entity=$2y$10$O5Q0sY7jKXzLB7zyH6dYbOdmLo6ksVN1HQejGCH7ms/x5JPNV3pC6)
ORDER OF SUSPENSION AND NOTICE OF HEARING Case No. 24-53587-1, -2 & -3 October 11, 2024 The Investigative Committee of the Nevada State Board of Medical Examiners suspended Hisbay Haider Ali, M.D.'s license to practice medicine in the State of Nevada pursuant to Nevada Revised Statute 630.326(1). Order: four (4) pages.	Order of Summary Suspension and Notice of Hearing - 24-53587-1,-2,-3.pdf (/rest/public/data/downloadannotation/index.php?id=67097b664d8f50214492359d&entity=$2y$10$iK8OeRacW6jmqcvlCsapKeJJIA8uEEha7ecla5hMBK9EphYm.41Xi)

Summary	Attachments
SETTLEMENT AGREEMENT AND ORDER Case Nos. 24-53587-1, 24-53587-2, and 24-53587-3 June 6, 2025 On June 6, 2025, the Nevada State Board of Medical Examiners (Board) accepted and approved a Settlement Agreement which allowed for an order to be entered finding that Dr. Ali violated NRS 630.304(5), NRS 630.301(5) and NRS 630.304(7), as set forth in Counts II, III and VII of the Complaint in Case No. 24-53587-1, NRS 630.301(4) and NRS 630.3062(1)(a), as set forth in Counts I and II of the Complaint in Case No. 24-53587-2, and NRS 630.306(1)(l), as set forth in Counts II and III of the Complaint in Case No. 24-53587-3, and ordered the following: Dr. Ali shall receive a public reprimand; pay a fine of $20,000 and reimburse the Board's costs and fees incurred in the investigation and prosecution of the case. Dr. Ali's license to practice medicine in the State of Nevada shall remain in suspended status for six months, with the lifting of the suspension contingent upon the following terms: Dr. Ali shall pass without conditions the Professional Problem-Based Ethics Program (PROBE) offered by the Center for Personalized Education for Physicians (CPEP); be evaluated by a properly certified substance use disorder/detoxification technician and undergo a substance use disorder evaluation and follow the recommendations provided; undergo and pass a fitness for duty evaluation to assess his competence and ability to safely and ethically practice medicine; and complete 20 hours of Continuing Medical Education (CME), in addition to his statutory CME requirements for licensure. Dr. Ali must always be accompanied by a chaperon during any and all interactions with female patients and shall not petition for removal of this condition for a minimum of three years. Dr. Ali's license shall be revoked for five years, with the revocation stayed and his license placed on probation for five years, subject to the following terms: Dr. Ali must be monitored by Strategic Management Services or another monitoring company approved by the Board, with chart reviews and quarterly reports to the Board, and shall obtain drug and alcohol counseling and	Settlement Agreement and Order - 24-53587-1,-2, and-3.pdf (/rest/public/data/downloadannotation/index.php?id=6855c6152f4f44afbfcf6852&entity=$2y$10$A/W4DhAf2NAIOB5TPt0kneYVhFDbmkG8gMjVwRURhRbzw/dNtpLca)

Summary	Attachments
remain in a drug and alcohol recovery program on at least a monthly basis for the duration of the probationary period. The remaining counts of the three Complaints were dismissed with prejudice. Settlement Agreement and Order: twelve (12) pages.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
Gardner, Reanna N/A	Primary Supervisor	Feb-06-2024
Fitsum, Salem G.	Primary Supervisor	Dec-27-2023
Frederic, Marjory N/A	Primary Supervisor	Jan-10-2024

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13B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)

☒ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)

Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☐ Schedule II ☒ Schedule III ☐ Schedule IV ☐ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Michael Middle: Stephen Patrick Last: Roach

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip Code: [redacted]

Telephone: [redacted] Email: mroach@mensdivision.org

APRN License #: 893125 Specialty: FNP

(A current license and active-PRESCRIBING status with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: Men's Divivion

Practice Address: 8905 W Post Rd Suite #: 110

City: Las Vegas State: NV Zip: 89148

Telephone: 725-726-6611 Fax: 8776340429 Email: mroach@mensdivision.org

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☒ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name: _____

Collaborating Physician Practice Address: _____ Suite #: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1/14/2020		TX	Houston	Harris

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
NA	Licensing (DEA)

Reason/Charge
Administrative Reason

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Men's T Clinic

Provide explanation below:

In 2020, I voluntarily reliquished my DEA license, for adminstrative reason based on clinical practice of Men's T Clinic, implemented a system wide change in policy subsquently changed the practice and avoided continued audit by the DEA, was re-instated 4/2020 (3month)
I have a current DEA License in Louisana MR6204995 and Texas MR5864497

Original Signature (electronic, copies or stamps not accepted)

11/17/2025
Date

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Olivia Mora

Subject: FW: Explanation

From: Michael Roach [redacted]
Sent: Tuesday, December 16, 2025 3:27 PM
To: Olivia Mora <o.mora@pharmacy.nv.gov>
Subject: Explanation

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

In 2022, I voluntarily relinquished my license, for administrative reason, reinstated 4/2020 (3month)

The follow codes are the violations that the clinic were sited to be in violation:

(page 73) CRF 1304.11 (a) Inventory Requirements

(page 73) CFR 1304.11 (b) Initial Inventories

(page 73) CFR 1304.11 (c) Biennial Inventories

(page 73)CFR 1304.11 (d) Newly Controlled Substances

(page 76) CFR 1304.22 requirements for documenting invoices of controlled substances.

(page 70) CFR 1304.04 (a) Theft and Loss Reports

(page 56) CFR 1301.76 (b) DEA 106

(page 76) CFR 1304.21 (d) DEA 41, drug destruction

The overall result of miss management of the regulatory process of managing controlled substances in the office.

I was an employee of Men's T Clinic, performing duties as their clinical director and Nurse Practitioner.

Ultimately, we were cited for not being managed by the Supervising Physician/Organization and policies were not implemented to ensure that we (as a company 6 clinics) were compliant.

Over a 3 month timeline I personally changed the company's policy, trained the staff and the Supervising Physician on the proper guidelines and practice.

I worked with Agent Carmen Mann to ensure the policies were accurate and correct.

Because of my efforts and cooperation I was reinstated in 3 months from the time of the occurrence.

I have maintained my DEA License ever since, in the state of Texas and Louisiana.

I am currently in good standing in both states.

I hope this clarifies the occurrence.

If you have any questions or concerns please contact me via email or phone.

Thank you

Michael Roach, FNP-BC

[redacted]

On Tue, Dec 16, 2025 at 5:04 PM Olivia Mora <o.mora@pharmacy.nv.gov> wrote:

Hi,

Can you please email the documentation? It seems that we are missing some information.

Thank you,

Olivia Mora

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440 x122

Sent from my iPhone

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Roach, FNP-BC

Applicant Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/17/2025

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: 11/24/25 Amount: $200 CC ✓

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

MICHAEL STEPHEN PATRICK ROACH [NCSBN ID: 20214108]

Thursday, December 18 2025 07:34:05 AM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to c protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, an provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing ve they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
ROACH, MICHAEL STEPHEN PATRICK	RN	893125	Inactive	08/15/2025	11/07/2025	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
ROACH, MICHAEL STEPHEN PATRICK	APRN-CNP	893125	Inactive	08/20/2025	11/12/2025	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Advanced Practice license/recognition information

- **Population Focus / Specialty:**
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 11/12/2025
  - Original Issuance Date: 08/20/2025
  - Current Issue Date: 08/20/2025
  - Certification expiration date: 03/31/2026

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
ROACH, MICHAEL STEPHEN PATRICK	RN	893125	Active	11/07/2025	11/22/2027	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
ROACH, MICHAEL STEPHEN PATRICK	APRN-CNP	893125	Active - Prescribing	11/12/2025	11/22/2027	NO

Advanced Practice license/recognition information

- **Population Focus / Specialty:**
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 11/22/2027
  - Original Issuance Date: 11/12/2025
  - Current Issue Date: 11/12/2025
  - Certification expiration date: 03/31/2026

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

13C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information

First: Orlandis Middle: Lamar Last: Wells

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: 10558 Specialty: Gynecology

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Hormone Therapy Institute

Practice Address: 2367 W Horizon Ridge Parkway Suite #: 130

City: Henderson State: NV Zip: 89052

Telephone: 702-568-6108 Fax: 702-947-4881 Email: owells@cox.net

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/16/2023		NV	Henderson	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:19-CR 00216	US Department of Justice-FBI

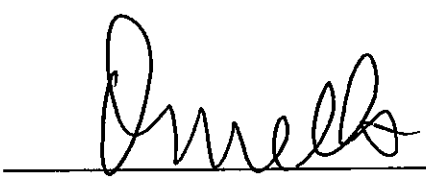
Reason/Charge
violation of 21 U.S.C. Controlled Substance Act

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
United States vs Orlandis Wells MD	

Name of Business/Industry/Entity

Provide explanation below:

Question #2: On 08/21/2019 I was arrested and indicted by the FBI for violation of the controlled substance act in the state of Nevada. The charge accusations were I prescribed controlled medications without a legitimate medical purpose and outside the usual course of professional practice. However, on 05/10/2023 the indictment was dismissed without prejudice as the indictment failed to allege that I knowingly and intentionally acted without authorization. The government initially decided to appeal the ruling but subsequently withdrew their appeal with the 9th Circuit.



Original Signature (electronic, copies or stamps not accepted)

11/12/2025

Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✔	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section S of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # 3 & 4 . Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
11/16/2023		NV	Henderson	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
23-28073-1, 23-28073-2	NSBME (Nevada State Board of Medical Examiners)

Reason/Charge
Malpractice, Failure to Maintain Proper Medical Records, Violation of Standards of Practice, Failure to exercise skill

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

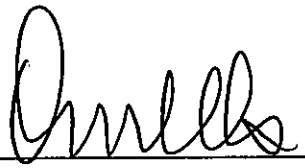
Name of Business/Industry/Entity

Provide explanation below:

Question #3: On 11/16/2023, I was served with a formal complaint from the NSBME. This complaint came after the dismissal of my indictment of charges from the federal government. The basis of the complaints was the prescribing of controlled substances by an OB/GYN. I have informed the board on several occasions that I no longer practice this style of medicine but a preventative and wellness based model consisting of functional and integrative medicine. However , on June 7, 2023, I entered into a settlement agreement with the board. The agreement called for revoking of my license which was stayed, two years of active probation with a provision for early release after 12 months, if all conditions are satisfied, a $25,000 fine, and I could not apply for my controlled substances or DEA license for one year. I was to also complete 22 hours of CME credits in Proper prescribing (which I have completed) and take the CPEP Probe Ethics course, which I am scheduled for November 13-15, 2025. I will also be petitioning the board to appear on the December 2025 agenda for early release of probation as all requirements will have been fulfilled. I will be attaching the complaints, settlement agreement, CME certificate, and my personal protection plan that I created after completion of the Proper prescribing course.

Question #4: I didn't really know how to answer this question, but as a precaution I answered yes. I didn't know if the NSBME complaints are considered as discipline for violation of pharmacy or drug laws. It has never been stated that I was being disciplined for either of these violations. If the complaints are consistent with these violations then I would refer to the answers in question 3. Again, I have taken the Proper prescriber course and created a personal protection plan, both of which I will be attaching.

As an aside, I was issued an controlled substance license on 08/04/2023 after the federal charges were dismissed. However, the DEA would not approve my application after collaborating with the NSBME to file the above complaints. I had to let the CS license expire as the DEA asked me to withdraw my application



Original Signature (electronic, copies or stamps not accepted)

11/12/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Orlandis Wells	11/12/2025
Print Name (First, Last)	Date
Original Signature (electronic, copies or stamps not accepted)	11/12/2025
	Date

Board Use Only: Date Processed: 11/17/25 Amount: $200 Ch 1164

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, v. ORLANDIS WELLS, MD, Defendant.	Case No. 2:19-cr-00216-ART-NJK ORDER

Before the Court is Wells' motion to dismiss (ECF No. 85) and supplemental motions to dismiss (ECF No. 108) arguing that the Indictment fails to state an offense. For the reasons set forth below, Wells' motion is granted.

I. Procedural History

Dr. Wells, a Board-Certified Physician generally authorized to prescribe controlled substances to patients, was indicted on August 21, 2019, on thirty-two counts of violating 21 § U.S.C. 841(a)(1) and (b)(1)(C). (ECF No. 1.)

On December 1, 2022 (ECF No. 85), Wells filed a motion to dismiss. The government responded. (ECF No. 89.) Wells replied. (ECF No. 96.)

On February 17, 2023, Wells and the government filed supplemental briefing (ECF Nos. 108; 109) pursuant to the Court's Minute Order, which requested the parties address two Ninth Circuit cases. (ECF No. 106.)

The Court held an oral argument on February 24, 2023 (ECF No. 111). Following oral argument, the parties submitted additional supplemental briefing. (ECF Nos. 113; 114.) This order follows.

II. Legal Standard

A defendant may challenge the sufficiency of an indictment prior to trial for failure to state an offense. FED. R. CRIM. P. 12(b)(v). It is "axiomatic" that an indictment must set forth each and every element of the offense, including

implied, necessary elements, to adequately allege an offense against the United States. *See United States v. Davis*, 33 F.4th 1236, 1240 (9th Cir. 2022). "An indictment is sufficient if it contains the elements of the charged crime in adequate detail to inform the defendant of the charge and to enable him to plead double jeopardy." *United States v. Lopez*, 576 F. App'x 680, 681–82 (9th Cir. 2014) (quoting *United States v. Awad*, 551 F.3d 930, 935 (9th Cir. 2009)). "The failure of an indictment to detail each element of the charged offense generally constitutes a fatal defect." *United States v. Keith*, 605 F.2d 462, 464 (9th Cir. 1979). This is true even when an indictment "tracks the language of a statute." *Id.* In the end, a person "cannot be convicted on the basis of facts not found by, and perhaps not even presented to, the grand jury." *Id.*

"The test for sufficiency of the indictment is 'not whether it could have been framed in a more satisfactory manner, but whether it conforms to minimal constitutional standards.'" *Awad*, 551 F.3d at 935. When determining whether an indictment states a cognizable offense, courts are "bound by the four corners of the indictment, must accept the truth of the allegations in the indictment, and cannot consider evidence that does not appear on the face of the indictment." *United States v. Kelly*, 874 F.3d 1037, 1047 (9th Cir. 2017).

"[A]n indictment's complete failure to recite an essential element of the charged offense is . . . a fatal flaw requiring dismissal of the indictment." *United States v. Du Bo*, 186 F.3d 1177, 1179 (9th Cir. 1999); *see also United States v. Qazi*, 975 F.3d 989, 993 (9th Cir. 2020) (noting that an omission of an essential element is one "of at least two reasons why an indictment may fail to state an offense."). While "minor or technical deficiencies, even where the errors are related to an element of the offense charged . . . are amenable to harmless error review," a "completely missing essential element" renders an indictment constitutionally defective. *Du Bo*, 186 F.3d at 1180 (internal quotations and citations omitted).

III. Discussion

Wells challenges the sufficiency of the Indictment based on *Ruan v. United States*, 142 S. Ct. 2370 (2022), a case that was decided after Wells was indicted and altered what the Government must prove to convict a physician of violating 21 U.S.C. § 841(a)(1) and (b)(1)(C). Section 841 provides that "[e]xcept as authorized . . . it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance." [add citation] A prescription is "authorized" if it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his [or her] professional practice." 21 C.F.R. § 1306.04(a) (2021). In *Ruan*, the Supreme Court held that the knowingly or intentionally mens rea applies to "except as authorized" clause.

The Supreme Court's decision in *Ruan* altered what the Government must prove under § 841, but it is not clear whether *Ruan* changed what the Government must plead. This uncertainty stems from the fact that *Ruan* did not squarely find that § 841's "except as authorized" clause is an element of the offense. *Ruan*, 142 S. Ct. at 2380. One of the ways the Government and the concurrence in *Ruan* argued that the "except as authorized" clause differs from a traditional element stems from the operation of 21 U.S.C. § 885, which provides that the Government does not need to anticipate or foreclose affirmative defenses. Section 885 states, "[i]t shall not be necessary for the United States to negative any exemption or exception set forth in this subchapter in any . . . indictment or other pleading or in any trial . . . ." Section 885 also establishes that "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit." *Id.*

The government argued in *Ruan* that "except as authorized" is not an element because under § 885, the "government need not refer to a lack of authorization (or any other exemption or exception) in the criminal indictment." *Id.* at 2379. The Court noted that "Section 885 merely absolves the Government

of having to allege, in an indictment, the inapplicability of *every statutory exception* in each Controlled Substances Act prosecution." *Id.* at 2380 (emphasis added). The Court held that "even assuming that lack of authorization is unlike an element" for the purposes of § 885, "it is sufficiently like an element in respect to [scienter requirements] as to warrant similar treatment." *Id.* at 2379–80. The Court did not clarify how far this similar treatment extends. *See id.* at 2383 (Alito, J., concurring) ("How many other affirmative defenses might warrant similar treatment, the Court does not say. It leaves prosecutors, defense attorneys, and the lower courts in the dark.").

Since *Ruan* at least one district court has held that *Ruan* does require the Government to plead in the indictment that the defendant knowingly or intentionally acted in an unauthorized manner. *See United States v. Spayd*, 2022 WL 4220192 (D. Alaska Sept. 13, 2022); *but see United States v. Spivack, et al.*, No. CV 22-343, 2022 WL 4091669, at *1 n.1 (E.D. Pa. Sept. 6, 2022); *United States v. Siefert, et al.*, No. 2:21-cr-00002-DLB-CJS (E.D. Ky. Feb 24, 2021). The district court in *Spayd* concluded that the element added by *Ruan* was alleged in the superseding indictment, which alleged that Ms. Spayd, "while acting *and intending to act* outside the usual course of professional practice and without a legitimate medical purpose, wrote and dispensed prescriptions" for controlled substances. *Id.* at *3.

Before *Ruan*, the Ninth Circuit held that "except as authorized" is an element of the offense when a medical practitioner is criminally prosecuted under § 841.[1] In *United States v. King*, 587 F.2d 956 (9th Cir. 1978), the Court held that a controlled substance offense indictment against a medical practitioner must allege that the physician acted without authorization. *Id.* at 1548. *King* held that

[1] The district Court in *Spayd* appears to have reached its conclusion without considering, or at least discussing, the fact that the Ninth Circuit had already held that in the narrow circumstance of a medical professional charged with violating § 841, "except as authorized" is treated like an element for both indictment and trial purposes.

registered medical practitioners who dispense controlled substances cannot be presumed to do so unlawfully when the defendant is a physician duly registered with the Attorney General to dispense controlled substances. *Id.* at 1548. Such a presumption is irrational, and hence unconstitutional, the court explained in *King*, because it could not say with substantial assurance that the presumed fact of non-authorization is more likely than not to flow from the distribution by a practitioner. *Id.* The Ninth Circuit confirmed in *United States v. Kim* that the "except as authorized" element must be pled in an indictment when a doctor is indicted, as failing to do so deprives the defendant of notice. 298 F.3d 746, 750 (9th Cir. 2002) ("Assuming as we must that *King* is good law, its rationale applies to a physician charged with distributing an unknown quantity of a drug; the case holds that he could not be presumed to have acted beyond his authorization unless the indictment so alleged."). Nothing in *Ruan* calls into question that line of cases.

Because "except as authorized" is already an element in the Ninth Circuit, *Ruan's* holding requires that indictments of medical practitioners under § 841 allege that a medical practitioner "knowingly and intentionally" acted without authorization. This follows from the Ninth Circuit's holdings in *Rehaif v. United States*, 139 S. Ct. 2191 (2019) and *United States v. Qazi*, 975 F.3d 989, 992 (9th Cir. 2020), which addressed an analogous development in how the government was required to prove and indict the crime of felon in possession of a firearm. The federal statute in *Rehaif*, 18 U.S.C. § 922(g), provides that "[i]t shall be unlawful" for certain individuals to possess firearms and lists categories of individuals subject to the prohibition. A separate provision, § 924(a)(2), adds that anyone who "knowingly violates" the first provision shall be fined or imprisoned for up to 10 years. The Court held in *Rehaif* that to convict, the Government must show that the defendant knew he possessed a firearm and knew he had the relevant status when he possessed it. *Rehaif v. United States*, 139 S. Ct. 2191, 2194

(2019).

Following *Rehaif*, the court in *Qazi* required that indictments charge a defendant's knowledge of their prohibited status. The defendant in *Qazi* was charged with being a felon in possession of a firearm in violation of 18 U.S.C. § 922(g). *Qazi*, 975 F.3d at 994. Before trial, Qazi filed a "Motion to Dismiss Indictment for Failure to State Offense". *Id.* The government opposed Qazi's motion, arguing that the indictment tracks the language of 18 U.S.C. 922(g), sets forth the elements of the offense and clearly apprises the defendant of the charge that he must defend against. *Id.* The magistrate judge agreed with the government and concluded: "Here, the indictment tracks the language of 18 U.S.C. 922(g), sets forth the elements of the offense. This is sufficient." *Id.* While Qazi's appeal was pending, the Supreme Court recognized for the first time that the defendant's knowledge of his felon status is a required element under Section 922(g). *Id.* (citing *Rehaif*, 139 S. Ct. at 2200). Qazi's indictment did not contain this element. The court in *Qazi* found that the indictment neither "track[ed] the language of 18 U.S.C. 922(g)" nor "set[] forth the elements of the offense," because it did not allege that he had knowledge of his felon status. *Qazi*, 975 F.3d at 994. The court explained, "When the Supreme Court interprets a criminal statute in a way that narrows the scope of criminal conduct, we view the statute as always having meant what the Supreme Court now says it does." *Id.* at n.3.

The Indictment here does not allege that Dr. Wells knowingly and intentionally acted in an unauthorized manner. Introductory allegation 1 states that, "With limited exceptions for medical professionals, the CSA (Controlled Substance Act) makes it "unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance." (ECF No. 1 at 2.) Introductory allegation 8 states in relevant part that, "in order for a prescription for a controlled substance to be valid, it 'must be for a legitimate medical purpose by an individual practitioner practicing in the usual course of

his professional practice. (*Id.* at 4.) Introductory allegation 9 states that, "a prescription for a controlled substance issued without a legitimate medical purpose or outside of the individual practitioner's usual course of practice is not a valid prescription and the person who issues the prescription violates Title 21, United States Code, Section 841(a)(1). (*Id.* at 4.) The substantive counts incorporate the introductory allegations and further allege that Dr. Wells "did knowingly and intentionally distribute a mixture and substance containing a detectable amount of Schedule II controlled substance . . . without a legitimate medical purpose and outside the usual course of professional practice." (*Id.*)

The Court does not find persuasive the government's argument that the indictment adequately includes the *mens rea* added by *Ruan*. The government's strongest argument is that a natural reading of the Indictment leads to the conclusion that the *Ruan*-added mens rea modifies the verb "distribution" and the clause "without a legitimate purpose and outside the usual course of professional practice." (ECF No. 109.) There are several shortcomings, however. The government's argument omits any analysis of introductory allegation 1, which applies the mens rea only to the verbs "manufacturing", "distributing", and "dispensing." It also ignores the circumstance that that as a matter of basic grammar, adverbs modify verbs, and thus "knowingly" and "intentionally" would not naturally modify the phrase "without a legitimate purpose and outside the usual course of professional practice". Notably, the concurrence in *Ruan* observed that, "As a matter of elementary syntax, the adverbs "knowingly" and "intentionally" are most naturally understood to modify the verbs that follow, i.e., "manufacture," "distribute," etc. . . ." *Ruan*, 142 S. Ct. at 2384 (Alito, J., concurring).

Construing the Indictment as a whole and "in accord with common sense and practicality," *United States v. Holden*, 806 F.3d 1227, 1233 (9th Cir. 2015) (quoting *United States v. Alber*, 56 F.3d 1106, 1111 (9th Cir. 1995)), the new

element that *Ruan* added was not included in the Indictment. The "knowingly and intentionally" mens rea clearly applies to the act of distribution but not to the language defining without authorization. The Indictment is therefore facially invalid. The government in another district reached the same conclusion and elected to dismiss a similar indictment based on *Ruan*. *See United States v. Kim*, No. CR-20-163-PRW (W.D. Okla. Jul. 29, 2022)("Based on this intervening Supreme Court ruling [citing *Ruan*], the United States has concluded that the Indictment is defective."). Here, the Indictment is defective because the *Ruan*-added mens rea, which is an element in the Ninth Circuit, is not sufficiently alleged.

IV. CONCLUSION

Absence of authorization, at least in the Ninth Circuit, is an element that must be alleged when indicting a medical practitioner under § 841. *Ruan's* holding thus requires that such indictments allege that a medical practitioner "knowingly and intentionally" acted without authorization. The indictment in this case, when read as a whole, fails to allege that Dr. Wells knowingly and intentionally acted without authorization. The Court thus dismisses the Indictment without prejudice.

IT IS THEREFORE ORDERED that the Defendant's motion to dismiss (ECF No. 85) and supplemental motion to dismiss (ECF No. 108) are GRANTED.

IT IS FURTHER ORDERED that the Defendant's motion to exclude (ECF No. 110) is DENIED AS MOOT.

IT IS FURTHER ORDERED that the government's motion in limine (ECF No. 112) is DENIED AS MOOT.

DATED THIS 10th day of May 2023.

ANNE R. TRAUM
UNITED STATES DISTRICT JUDGE

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **ORLANDO LAMAR WELLS, M.D., Respondent.**	**Case No. 23-28073-1**

FILED
NOV 19 [illegible]

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, Senior Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Orlandis Lamar Wells, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a medical doctor holding an active license to practice medicine in the State of Nevada (License No. 10558). Respondent was originally licensed by the Board on July 7, 2003.

2. Patients A-I[2] were all patients of Respondent at various times while Respondent held an active license to practice medicine in the State of Nevada.

3. Patient A was a twenty-five (25) year-old female at the time of the events at issue and was a patient of Respondent from on or about October 6, 2015, to on or about October 6, 2016.

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Rachakonda D. Prabhu, M.D., Ms. Sandy Peltyn and Victor M. Muro, M.D.

[2] Patient A's through Patient I's true identities are not disclosed herein to protect their privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

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4. Patient B was a thirty-eight (38) year-old male at the time of the events at issue and was a patient of Respondent from on or about June 2, 2016, to on or about October 6, 2016.

5. Patient C was a twenty-eight (28) year-old female at the time of the events at issue and was a patient of Respondent from on or about June 2, 2016, to on or about October 20, 2016.

6. Patient D was a thirty (30) year-old male at the time of the events at issue and was a patient of Respondent from on or about May 26, 2016, to on or about September 19, 2016.

7. Patient E was a thirty (30) year-old female at the time of the events at issue and was a patient of Respondent from on or about June 17, 2016, to on or about October 3, 2016.

8. Patient F was a forty (40) year-old male at the time of the events at issue and was a patient of Respondent from on or about June 16, 2016, to on or about October 3, 2016.

9. Patient G was a thirty-five (35) year-old female at the time of the events at issue and was a patient of Respondent from on or about June 2, 2016, to on or about October 6, 2016.

10. Patient H was a twenty-nine (29) year-old male at the time of the events at issue and was a patient of Respondent from on or about March 8, 2016, to on or about May 5, 2016.

11. Patient I was a forty-one (41) year-old female at the time of the events at issue and was a patient of Respondent from on or about May 25, 2016, to on or about October 17, 2016.

12. Eight (8) of the nine (9) patients' records were nearly identical with regards to the physical exam and plan sections (demonstrating a lack of individual care for each of the nine (9) patients); Respondent occasionally prescribed methadone for all patients except Patient I as needed for pain and oxycodone for all patients as needed for pain, which is extremely dangerous and also demonstrates a failure to maintain proper medical records, as medical records when compared to prescriptions show these incongruencies; there is no indication that Respondent utilized urine drug screening to ensure compliance with the patients' pain medications; except for Patient H[3], and Respondent documented that the other eight (8) patients had nearly identical physical exams and diagnoses, resulting from the same straight leg tests and the FABER tests.

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[3] Upon information and belief, Respondent did not have access to Patient H's medical records and therefore he did not provide them.

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COUNTS I – IX (Patients A – I)

NRS 630.301(4) - Malpractice

13. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

14. NRS 630.301(4) provides that malpractice of a Physician is grounds for initiating disciplinary action against a licensee.

15. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

16. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patients A-I, when he failed to comply with the *Guidelines for the Chronic Use of Opioid Analgesics*, the vast majority of his documentation was copied and pasted for nearly all patients except Patient H, Respondent failed to give these nine (9) patients individualized care (the plan in his medical records for all patients were identical), and at times he prescribed methadone as needed for pain and oxycodone as needed for pain, which is extremely dangerous due to elevated risk of overdose.

17. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNTS X – XVII (Patients A – G and I)

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

18. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

19. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

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20. Respondent failed to maintain accurate and complete medical records relating to the diagnosis, treatment and care of Patients A – G and I, when he copied and pasted the medical records of these patients, resulting in nearly identical records for all nine (9) patients.

21. Respondent occasionally prescribed methadone for all patients except Patient I as needed for pain and oxycodone as needed for pain for all patients, which is extremely dangerous and also demonstrates a failure to maintain proper medical records, as medical records when compared to prescriptions show these incongruencies.

22. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNTS XVIII – XXVI (Patients A – I)

NRS 630.306(1)(b)(2) - Violation of Standards of Practice

23. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

24. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

25. The Board adopted by reference the Model Policy in NAC 630.187.

26. Pursuant to NAC 630.230(1)(k), a licensee shall not engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the standards set forth in the Model Policy.

27. As demonstrated by, but not limited to, the above-outlined facts, Respondent wrote prescriptions to Patients A - I for opioid analgesics to treat chronic pain in a manner that deviated from the Model Policy when he did not provide individualized care to each of the nine (9) patients, prescribed methadone and oxycodone to be taken as needed which is extremely dangerous, failed to obtain informed consent from some patients, and inappropriately continued these nine (9) patients on relatively high doses of opioids with little or no justification in the medical records, which were copied and pasted resulting in nearly identical diagnoses and treatment plans.

28. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNTS XXVII – XXXV (Patients A – I)

NRS 630.306(1)(g) - Continual Failure to Exercise Skill or Diligence

29. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

30. Continual failure by the Respondent to exercise the skill or diligence or use the methods ordinarily exercised under the same circumstances by physicians in good standing practicing in the same specialty or field is grounds for disciplinary action against a licensee pursuant to NRS 630.306(1)(g)

31. Respondent continually failed to exercise skill or diligence when he failed to comply with the *Guidelines for the Chronic Use of Opioid Analgesics*, the vast majority of his documentation was copied and pasted for all patients, Respondent failed to give these nine (9) patients individualized care (the plan in his medical records for all patients were identical), at times he prescribed methadone as needed, which is extremely dangerous due to elevated risk of overdose, failed to obtain informed consent from some patients, and inappropriately continued these nine (9) patients on relatively high doses of opioids with little or no justification in the medical records, which were copied and pasted resulting in nearly identical diagnoses and treatment plans.

32. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

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3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 16th day of November, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DONALD K. WHITE
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
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VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Chowdhury H. Ahsan, M.D., Ph.D., FACC, having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 16th day of November, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
CHOWDHURY H. AHSAN, M.D., PhD., FACC
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **ORLANDO LAMAR WELLS, M.D., Respondent.**	**Case No. 23-28073-2**

FILED
NOV 16 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

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Nevada State Board of Medical Examiners
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Reno, Nevada 89521
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COMPLAINT

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, Senior Deputy General Counsel and attorney for the IC, having a reasonable basis to believe that Orlandis Lamar Wells, M.D. (Respondent) violated the provisions of Nevada Revised Statutes (NRS) Chapter 630 and Nevada Administrative Code (NAC) Chapter 630 (collectively, the Medical Practice Act), hereby issues its Complaint, stating the IC's charges and allegations as follows:

1. Respondent was at all times relative to this Complaint a medical doctor holding an active license to practice medicine in the State of Nevada (License No. 10558). Respondent was originally licensed by the Board on July 7, 2003.

PATIENT A

2. Patient A[2] was a twenty-five (25) year-old female at the time of the events at issue.

3. Respondent treated Patient A from in or about August 2016 to in or about December 2016, at his office, namely Hormone Centers of Nevada.

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners, at the time this formal Complaint was authorized for filing, was composed of Board members Rachakonda D. Prabhu, M.D., Ms. Sandy Peltyn and Victor M. Muro, M.D.

[2] Patient A's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

4. Although Patient A had earlier encounters with Respondent at another office, it appears that her initial visit to Respondent at Hormone Centers of Nevada was on or about September 12, 2016, wherein she complained of chronic pain.

5. Patient A was already taking 30 mg of oxycodone and 350 mg of carisoprodol for approximately two (2) years. In addition, she was prescribed 5 mg methadone "as needed" and 10 mg methadone "as needed" for over one (1) year.

6. Patient A visited Respondent three (3) more times, on or about October 13, 2016, on or about November 10, 2016, and on or about December 19, 2016.

7. Respondent's documentation for each visit for Patient A was virtually identical and fails to justify the continued prescriptions for high doses of opioids, nor did he create a plan to investigate the cause of Patient A's chronic pain.

8. Respondent's documentation does not reflect that he attempted to obtain Patient A's records from previous providers.

9. Respondent's documentation does not reflect that he utilized imaging studies to determine the cause of Patient A's chronic pain.

10. Respondent's documentation does not reflect that he attempted to utilize alternative treatment (non-opioid) for Patient A's chronic pain.

11. Respondent's documentation indicates, "drug screen appropriate for meds prescribed," but test results are not included in the records for Patient A.

12. Respondent provided inadequate attention to an initial assessment to determine if opioids were clinically indicated and to determine the risks associated with their use in a particular individual with pain with regard to Patient A's medical care.

13. Respondent provided inadequate monitoring of Patient A during the utilization of medications that have the strong potential for misuse.

14. Respondent provided inadequate attention to patient education and informed consent for Patient A's medical care.

15. Respondent failed to justify dose escalation without properly counseling Patient A of the potential risks or alternative treatments.

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16. Respondent excessively relied on opioids, particularly high dose opioids for chronic pain management with regard to Patient A.

17. Respondent did not make use of available tools for risk mitigation with regard to Patient A.

COUNT I

NRS 630.301(4) - Malpractice

18. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

19. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

20. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

21. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient A when the records for each of Patient A's visits were nearly identical, when Respondent failed to obtain Patient A's medical records from previous providers, when Respondent failed to utilize imaging studies to determine the cause of Patient A's chronic pain, when Respondent failed to utilize alternative treatment options (non-opioid) for Patient A's chronic pain, and when Respondent failed to utilize drug screening to determine the appropriate prescriptions for Patient A.

22. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT II

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

23. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

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24. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

25. Respondent failed to maintain accurate and complete medical records relating to the diagnosis, treatment and care of Patient A, by documenting for each visit virtually identical records and failing to justify continued prescriptions for high doses of opioids.

26. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT III

NRS 630.306(1)(b)(2) - Violation of Standards of Practice

27. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

28. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

29. The Board adopted by reference the Model Policy in NAC 630.187.

30. Pursuant to NAC 630.230(1)(k), a licensee shall not engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the standards set forth in the Model Policy.

31. As demonstrated by, but not limited to, the above-outlined facts, Respondent wrote prescriptions to Patient A for opioid analgesics to treat chronic pain in a manner that deviated from the Model Policy when the records for each of Patient A's visits were nearly identical, when Respondent failed to obtain Patient A's medical records from previous providers, failed to utilize imaging studies to determine the cause of Patient A's chronic pain, failed to utilize alternative treatment (non-opioid) for Patient A's chronic pain, and failed to utilize drug screening to determine the appropriate prescriptions for Patient A.

32. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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COUNT IV

NRS 630.306(1)(c) – Unlawful Prescribing of Controlled Substance or Dangerous Drug

33. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

34. NRS 630.306(1)(c) provides that administering, dispensing or prescribing any controlled substance, or any dangerous drug as defined in chapter 454 of NRS, to or for himself or herself or to others except as authorized by law, constitute grounds for initiating disciplinary action.

35. NRS 453.381(1) provides in part that, ... a physician may prescribe controlled substances only for a legitimate medical purpose and in the usual course of his or her professional practice....

36. Respondent did not "prescribe controlled substances only for a legitimate medical purpose," making these prescriptions unlawful pursuant to NRS 630.306(1)(c).

37. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

PATIENT B

38. Patient B[3] was a forty-one (41) year old male at the time of the events at issue.

39. Respondent treated Patient B from on or about January 2, 2017, to on or about January 30, 2017, at his office, Hormone Centers of Nevada.

40. Patient B's January 2, 2017, progress note does not indicate that this was his first visit with Respondent.

41. The medical records for Patient B's two (2) separate visits are identical and they are strikingly similar to Patient A's medical record.

42. Respondent prescribed Patient B 30 mg oxycodone and 10 mg for diazepam as early as March 14, 2016, but there is no documentation supporting the prescribing of high doses of 180 MME/day of oxycodone in combination with the diazepam.

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[3] Patient B's true identity is not disclosed herein to protect his privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

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43. Respondent had Patient B's MRI of the lumbar and cervical spine dated September 20, 2014, but no other previous records.

44. Respondent provided inadequate attention to Patient B's initial assessment in determining if opioids were clinically indicated nor determined the risks associated with their use in a particular individual with pain when he treated Patient B.

45. Respondent provided inadequate monitoring of Patient B during the utilization of medications that have the strong potential for misuse.

46. Respondent provided inadequate attention to patient education and informed consent for Patient B.

47. Respondent failed to justify dose escalation without adequate attention to the risks or alternative treatments with regard to Patient B.

48. Respondent excessively relied on opioids, particularly high dose opioids for chronic pain management with regard to Patient B.

49. Respondent did not make use of available tools for risk mitigation with regard to Patient B.

COUNT V

NRS 630.301(4) - Malpractice

50. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

51. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

52. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

53. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient B when the records for both of Patient B's visits were identical, when Respondent obtained one (1) previous MRI from Patient B's medical records from

previous providers, failed to utilize alternative treatment (non-opioid) for Patient B's chronic pain, and failed to utilize drug screening to determine the appropriate prescriptions for Patient B.

54. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT VI

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

55. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

56. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient," constitutes grounds for initiating discipline against a licensee.

57. Respondent failed to maintain accurate and complete medical records relating to the diagnosis, treatment and care of Patient B, by documenting for both visits identical records and failing to justify continued prescriptions for high doses of opioids.

58. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT VII

NRS 630.306(1)(b)(2) - Violation of Standards of Practice

59. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

60. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

61. The Board adopted by reference the Model Policy in NAC 630.187.

62. Pursuant to NAC 630.230(1)(k), a licensee shall not engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the standards set forth in the Model Policy.

63. As demonstrated by, but not limited to, the above-outlined facts, Respondent wrote prescriptions for Patient B for opioid analgesics to treat chronic pain in a manner that deviated

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from the Model Policy. Respondent's deviations include but are not limited to when the records for both of Patient B's visits were identical, when Respondent failed to obtain all but one (an MRI) of Patient B's medical records from previous providers, when Respondent failed to utilize alternative treatment (non-opioid) for Patient B's chronic pain, and when Respondent failed to utilize drug screening to determine the appropriate prescriptions for Patient B.

64. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT VIII

NRS 630.306(1)(c) – Unlawful Prescribing of Controlled Substance or Dangerous Drug

65. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

66. NRS 630.306(1)(c) provides that administering, dispensing or prescribing any controlled substance, or any dangerous drug as defined in chapter 454 of NRS, to or for himself or herself or to others except as authorized by law, constitute grounds for initiating disciplinary action.

67. NRS 453.381(1) provides in part that, ... a physician may prescribe controlled substances only for a legitimate medical purpose and in the usual course of his or her professional practice....

68. Respondent did not "prescribe controlled substances only for a legitimate medical purpose," making these prescriptions unlawful pursuant to NRS 630.306(1)(c).

69. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

PATIENT C

70. Patient C[4] was a forty (40) year-old female at the time of the events at issue.

71. Respondent treated Patient C from on or about September 22, 2016, to on or about February 16, 2017, at his office, Hormone Centers of Nevada.

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[4] Patient C's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

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72. Patient C visited Respondent at Hormone Centers of Nevada three (3) times, on or about December 15, 2016, on or about January 19, 2017, and on or about February 16, 2017.

73. Patient C was prescribed 30 mg oxycodone as early as May 2014.

74. Respondent's documentation for each visit is identical, fail to justify continued prescriptions for high doses of opioids, and they are identical to Patient A's notes.

75. Patient C's physical examination is identical to Patient A's.

76. A urine drug screen dated November 17, 2016, documented negative results for all substances tested including oxycodone, which should have alerted Respondent to potential misuse of oxycodone by Patient C.

77. Respondent's subsequent progress note dated December 15, 2016, failed to mention the negative test results, and in the alternative stated, "drug screen appropriate for meds prescribed." Respondent then prescribed an additional 30 mg oxycodone during this same visit.

78. Respondent's documentation does not reflect that he attempted to obtain Patient C's records from previous providers.

79. Respondent's documentation does not reflect that he utilized imaging studies to determine the cause of Patient C's chronic pain, nor any attempt by Respondent to consider alternate treatments for Patient C's chronic pain.

80. When treating Patient C, Respondent provided inadequate attention to initially assess and determine if opioids were clinically indicated or to determine the risks associated with their use by Patient C.

81. Respondent provided inadequate monitoring of Patient C during the utilization of medications that have the strong potential for misuse.

82. Respondent provided inadequate attention to patient education and informed consent for Patient C.

83. Respondent failed to justify dose escalation without adequate attention to risks or alternative treatments with regard to Patient C.

84. Respondent excessively relied on opioids, particularly high dose opioids for chronic pain management with regard to Patient C.

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85. Respondent did not make use of available tools for risk mitigation with regard to Patient C when beginning a regimen of strong opioid medication.

COUNT IX

NRS 630.301(4) - Malpractice

86. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

87. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

88. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

89. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient C when the records for Patient C's visits were identical for each visit and were identical to Patient A's records (including the physical examination); when Respondent failed to obtain Patient C's medical records from previous providers; when Respondent failed to utilize alternative treatment (non-opioid) for Patient C's chronic pain and failed to properly utilize drug screening to determine the appropriate prescriptions for Patient C when placing her on strong opioid medication.

90. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT X

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

91. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

92. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

93. Respondent failed to maintain accurate and complete medical records relating to the diagnosis, treatment and care of Patient C, by documenting identical records for each visit (and documenting the identical records as he did for Patient A) and failing to justify continued prescriptions for high doses of opioids.

94. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT XI

NRS 630.306(1)(b)(2) - Violation of Standards of Practice

95. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

96. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

97. The Board adopted by reference the Model Policy in NAC 630.187.

98. Pursuant to NAC 630.230(1)(k), a licensee shall not engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the standards set forth in the Model Policy.

99. As demonstrated by, but not limited to, the above-outlined facts, Respondent wrote prescriptions to Patient C for opioid analgesics to treat chronic pain in a manner that deviated from the Model Policy when the records for each of Patient C's visits were identical (and identical to Patient A's records), when Respondent failed to obtain Patient C's medical records from previous providers, when Respondent failed to utilize alternative treatment (non-opioid) for Patient C's chronic pain, and when Respondent failed to properly utilize drug screening to determine the appropriate prescriptions for Patient C.

100. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

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COUNT XII

NRS 630.306(1)(c) – Unlawful Prescribing of Controlled Substance or Dangerous Drug

101. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

102. NRS 630.306(1)(c) provides that administering, dispensing or prescribing any controlled substance, or any dangerous drug as defined in chapter 454 of NRS, to or for himself or herself or to others except as authorized by law, constitute grounds for initiating disciplinary action.

103. NRS 453.381(1) provides in part that, ... a physician may prescribe controlled substances only for a legitimate medical purpose and in the usual course of his or her professional practice....

104. Respondent did not prescribe controlled substances only for a legitimate medical purpose making these prescriptions unlawful pursuant to NRS 630.306(1)(c) when the records for each of Patient C's visits were identical to each other and to Patient A's medical records, when Respondent failed to obtain Patient C's medical records from previous providers, failed to utilize alternative treatment (non-opioid) for Patient C's chronic pain, and failed to properly utilize drug screening to determine the appropriate prescriptions for Patient C.

105. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

PATIENT D

106. Patient D[5] was a thirty-eight (38) year-old female at the time of the events at issue.

107. Respondent treated Patient D from on or about March 7, 2016, to on or about February 16, 2017, at his office, Hormone Centers of Nevada.

108. On March 7, 2016, Respondent prescribed Patient D 30 mg oxycodone and 350 mg carisoprodol which continued on a monthly basis until December 15, 2016.

109. Respondent also prescribed 10 mg diazepam to Patient D on March 7, 2016.

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[5] Patient D's true identity is not disclosed herein to protect her privacy, but is disclosed in the Patient Designation served upon Respondent along with a copy of this Complaint.

110. Patient D's progress notes were nearly identical to the progress notes of Patients A, B, and C.

111. A urine drug screen collected on November 17, 2016, was negative for oxycodone and not addressed in this visit nor subsequent visits. The negative result should have alerted Respondent to potential misuse of oxycodone by Patient D.

112. Instead, Respondent's subsequent progress notes dated December 15, 2016, January 17, 2017, and February 16, 2017, state, "[drug] screen appropriate for meds prescribed."

113. Respondent prescribed 30 mg oxycodone tablets on the same day as the negative result, December 15, 2016.

114. Respondent's documentation does not reflect that he attempted to obtain Patient D's records from previous providers nor did Respondent utilize imaging studies to determine the cause of Patient D's chronic pain.

115. Respondent's documentation does not reflect that he attempted to utilize alternative treatment (non-opioid) for Patient D's chronic pain.

116. Respondent provided inadequate attention to initial assessment to determining if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain with regard to Patient D.

117. Respondent provided inadequate monitoring of Patient D during the utilization of medications that have the strong potential for misuse.

118. Respondent provided inadequate attention to patient education and informed consent for Patient D.

119. Respondent failed to justify dose escalation without adequate attention to risks or alternative treatments with regard to Patient D.

120. Respondent excessively relied on opioids, particularly high dose opioids for chronic pain management with regard to Patient D.

121. Respondent did not make use of available tools for risk mitigation with regard to Patient D.

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COUNT XIII

NRS 630.301(4) - Malpractice

122. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

123. NRS 630.301(4) provides that malpractice of a physician is grounds for initiating disciplinary action against a licensee.

124. NAC 630.040 defines malpractice as "the failure of a physician, in treating a patient, to use the reasonable care, skill, or knowledge ordinarily used under similar circumstances."

125. As demonstrated by, but not limited to, the above-outlined facts, Respondent failed to use the reasonable care, skill or knowledge ordinarily used under similar circumstances when rendering medical services to Patient D when the records for Patient D's progress notes were nearly identical to the progress notes of Patients A, B and C, when Respondent failed to obtain Patient D's medical records from previous providers, failed to utilize alternative treatment (non-opioid) for Patient D's chronic pain, and failed to properly utilize drug screening to determine the appropriate prescriptions for Patient D.

126. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT XIV

NRS 630.3062(1)(a) - Failure to Maintain Proper Medical Records

127. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

128. NRS 630.3062(1)(a) provides that the "failure to maintain timely, legible, accurate and complete medical records relating to the diagnosis, treatment and care of a patient" constitute grounds for initiating discipline against a licensee.

129. Respondent failed to maintain accurate and complete medical records relating to the diagnosis, treatment and care of Patient D, by documenting progress notes for Patient C that were nearly identical to the progress notes for Patients A, B, and C, failing to justify continued

prescriptions for high doses of opioids, and failing to accurately document the results of Patient D's urine drug screen..

130. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT XV

NRS 630.306(1)(b)(2) - Violation of Standards of Practice

131. All of the allegations in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

132. Violation of a standard of practice adopted by the Board is grounds for disciplinary action pursuant to NRS 630.306(1)(b)(2).

133. The Board adopted by reference the Model Policy in NAC 630.187.

134. Pursuant to NAC 630.230(1)(k), a licensee shall not engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the standards set forth in the Model Policy.

135. As demonstrated by, but not limited to, the above-outlined facts, Respondent wrote prescriptions to Patient D for opioid analgesics to treat chronic pain in a manner that deviated from the Model Policy.

136. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

COUNT XVI

NRS 630.306(1)(c) – Unlawful Prescribing of Controlled Substance or Dangerous Drug

137. All of the allegations contained in the above paragraphs are hereby incorporated by reference as though fully set forth herein.

138. NRS 630.306(1)(c) provides that administering, dispensing or prescribing any controlled substance, or any dangerous drug as defined in chapter 454 of NRS, to or for himself or herself or to others except as authorized by law, constitute grounds for initiating disciplinary action.

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139. NRS 453.381(1) provides in part that, ... a physician may prescribe controlled substances only for a legitimate medical purpose and in the usual course of his or her professional practice....

140. Respondent did not "prescribe controlled substances only for a legitimate medical purpose," making these prescriptions unlawful pursuant to NRS 630.306(1)(c).

141. By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

WHEREFORE, the Investigative Committee prays:

1. That the Board give Respondent notice of the charges herein against him and give him notice that he may file an answer to the Complaint herein as set forth in NRS 630.339(2) within twenty (20) days of service of the Complaint;

2. That the Board set a time and place for a formal hearing after holding an Early Case Conference pursuant to NRS 630.339(3);

3. That the Board determine what sanctions to impose if it determines there has been a violation or violations of the Medical Practice Act committed by Respondent;

4. That the Board award fees and costs for the investigation and prosecution of this case as outlined in NRS 622.400;

5. That the Board make, issue and serve on Respondent its findings of fact, conclusions of law and order, in writing, that includes the sanctions imposed; and

6. That the Board take such other and further action as may be just and proper in these premises.

DATED this 16th day of November, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DONALD K. WHITE
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

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VERIFICATION

STATE OF NEVADA)
: ss.
COUNTY OF CLARK)

Chowdhury H. Ahsan, M.D., Ph.D., FACC, having been duly sworn, hereby deposes and states under penalty of perjury that he is the Chairman of the Investigative Committee of the Nevada State Board of Medical Examiners that authorized the Complaint against the Respondent herein; that he has read the foregoing Complaint; and that based upon information discovered in the course of the investigation into a complaint against Respondent, he believes that the allegations and charges in the foregoing Complaint against Respondent are true, accurate and correct.

DATED this 16th day of November, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
CHOWDHURY H. AHSAN, M.D., Ph.D., FACC
Chairman of the Investigative Committee

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BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaints Against: **ORLANDIS LAMAR WELLS, M.D.,** **Respondent.**	**Case Nos. 23-28073-1 & 23-28073-2**

FILED

JUN 07 2024

NEVADA STATE BOARD OF MEDICAL EXAMINERS

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Donald K. White, Senior Deputy General Counsel for the Board and attorney for the IC, and Orlandis Lamar Wells, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Maria Nutile, Esq., of the law firm of Nutile Law, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

1. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on July 7, 2003 (License No. 10558).

2. On November 16, 2023, in Case No. 23-28073-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges nine (9) violations of NRS 630.301(4), Malpractice (Counts I-IX); seven (7) violations of NRS 630.3062(1)(a) Failure to Maintain Proper Medical Records (Counts X-XVII); eight (8) violations of NRS 630.306(1)(b)(2) Violation of Standards of Practice, (Counts XVIII-

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

XXVI); eight (8) violations of NRS 630.306(1)(g) Continual Failure to exercise Skill or Diligence (Counts XXVII-XXXV).

3. On November 16, 2023, in Case No. 23-28073-2, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges four (4) violations of NRS 630.301(4), Malpractice (Counts I, V, IX, XIII); four (4) violations of NRS 630.3062(1)(a) Failure to Maintain Proper Medical Records (Counts II, VI, X, XIV); four (4) violations of NRS 630.306(1)(b)(2) Violation of Standards of Practice, (Counts III, VII, XI, XV); four (4) violations of NRS 630.306(1)(c) Unlawful Prescribing of Controlled Substance or Dangerous Drug (Counts IV, VIII, XII, XVI). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of both Complaints, has reviewed and understands both Complaints, and has had the opportunity to consult with competent counsel concerning the nature and significance of the Complaints.

5. Respondent is hereby advised of his rights regarding the administrative matters, and of his opportunity to defend against the allegations in the Complaints. Specifically, Respondent has certain rights in the administrative matters as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B and 622A. These rights include the right to a formal hearing on the allegations in the Complaints, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and orders reflecting the final decisions of the Board, and the right to judicial review of the Board's orders, if the decisions are adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of

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Nevada State Board of Medical Examiners
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Reno, Nevada 89521
(775) 688-2559

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administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaints, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaints has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that

may apply to him in connection with the administrative proceedings resulting from the Complaints filed in these matters, including defense of the Complaints, adjudication of the allegations set forth in the Complaints, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaints as set out by this Agreement, without hearings or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaints remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges Respondent is not admitting that the IC's claims/counts as alleged in the Complaints have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearings and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaints, but for the purposes of resolving these matters and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve these Complaints pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. In Case No. 23-28073-1, Respondent admits to Counts I – IV, four (4) violations of NRS 630.301(4); Counts X - XIII, four (4) violations of NRS 630.3062(1)(a); Counts XVIII – XXI, four (4) violations of NRS 630.306(1)(b)(2); and Counts XXVII – XXX, four (4) violations of NRS 630.306(1)(g).

b. In Case No. 23-28073-2, Respondent admits to Counts I, V, IX, and XIII, four (4) violations of NRS 630.301(4); and Counts IV, VIII, XII, and XVI, four (4) violations of NRS 630.306(1)(c).

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c. Respondent's license to practice medicine in the State of Nevada shall be revoked. The revocation is immediately stayed, and his license placed on probationary status for twenty-four (24) months, from the Board's acceptance, adoption and approval of this Agreement (Probationary Period). If the stay of revocation is lifted and Respondent's license is revoked pursuant to this Agreement, Respondent, pursuant to NRS 622A.410, may not apply for a new license for a period of one (1) year. For the first twelve (12) months of the Probationary Period, Respondent shall not petition the Board for early release from probation or its conditions.

d. During the Probationary Period, Respondent may not supervise any physician assistants or collaborate with any advanced practice registered nurses. Within fourteen (14) days from the Board's acceptance and adoption of this Agreement, Respondent shall terminate any current supervising agreements with physician assistants and any current collaboration agreements with advanced practice registered nurses.

e. After the first year of the Probationary Period, Respondent may petition the Board for early release from probation if he has complied with all of the terms of this Agreement but only after providing proof to the Board that he has successfully completed twenty-two (22) hours of Continuing Medical Education (CME) related to the subject of best practices in prescribing controlled substances and the PROBE program.

f. During the Probationary Period, Respondent agrees to not reapply for a license to prescribe controlled substances from the Nevada State Board of Pharmacy for at least one year from the date of the Board's acceptance, adoption and approval of this Agreement, and not until he successfully completes 22 hours Continued Medical Education related to the subject of best practices in prescribing controlled substances.

g. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter in the amount of ten thousand three hundred forty-seven dollars and sixty-five cents ($10,347.65) on or before August 7, 2024, contingent upon the Board's acceptance, adoption and approval of this Agreement.

h. Respondent shall pay a fine of twenty-five thousand dollars ($25,000.00) in twenty-four (24) equal monthly payments of one thousand forty-one dollars and sixty-seven cents

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($1,041.67) beginning on September 7, 2024. The payment plan is based on the Board's acceptance, adoption and approval of this Agreement.

i. The Respondent shall perform twenty-two (22) hours of Continuing Medical Education (CME) related to the subject of best practices in prescribing controlled substances before he applies for a license to prescribe controlled substances from the Nevada State Board of Pharmacy, and these CME hours shall be in addition to the required CMEs for licensure.

j. The Respondent shall enroll in and complete PROBE: Ethics and Boundaries Program within his 24-month Probationary Period.

k. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

l. Respondent shall receive a Public Letter of Reprimand.

m. The remaining counts of the Complaints, any other claims arising from the Board's corresponding investigative case files, as well as Investigative Case Nos. 17-17194 and 18-17704 shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, these investigations, this Agreement or the administration of the cases referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in

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resolution of these Complaints. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parte, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaints and any and all information of every nature whatsoever related to these matters. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaints shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering these Complaints and from participating in disciplinary proceedings against Respondent, including adjudication of the cases; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such

jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed. Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

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Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 15th day of May, 2024.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

DONALD K. WHITE
Senior Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: dwhite@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 10th day of May, 2024.

NUTILE LAW

By: _____

MARIA NUTILE, ESQ.
BRIDGET KELLY, ESQ.
7395 S. Pecos Road, Suite 103
Las Vegas, NV 89120
Tel: (702) 307-4880
Email: maria@nutilelaw.com
bridget@nutilelaw.com
Attorneys for Respondent

DATED this 9th day of May, 2024.

By: _____

ORLANDIS LAMAR WELLS, M.D.,
Nevada License No. 10558
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case Nos. 23-28073-1 and 23-28073-2) was approved and accepted by the Nevada State Board of Medical Examiners on the 7th day of June, 2024.

DATED this 7th day of June, 2024.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

NICK M. SPIRTOS, M.D., F.A.C.O.G.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

PBI EDUCATION

The University of California, Irvine School of Medicine certifies that

Orlandis Wells, MD

has participated in the Other/Blended Learning activity titled

PBI Proper Prescribing

on

October 25-26, 2025

and is awarded 21 AMA PRA Category 1 Credits™.

The University of California, Irvine School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Robert M McCarron DO.

Robert M. McCarron, D.O.
Profession, Department of Psychiatry and Human Behavior
Director of Education, Susan Samueli Integrative Health Institute
Associate Dean, Continuing Medical Education
Director, UCI Train New Trainer Primary Care Psychiatry Fellowship
University of California, Irvine School or Medicine

UCI Continuing Medical Education

This activity has been planned and implemented through the joint providership of the University of California, Irvine School of Medicine and Professional Boundaries, Inc. DBA PBI Education

PBI Education
www.pbieducation.com | (904) 800-1237 | info@pbieducation.com

Dr. Wells' Personal Protection Plan

I. Organizational

- Create a SOP for controlled substance prescribing (ex. Assessment, risks, monitoring, documentation, and refills)
- Review regulatory board's website quarterly requirements for in office dispensing
- Develop an updated informed consent and controlled substance agreement to reflect current guidelines and recommendations
- Incorporate more templates regarding different controlled substance therapies and improve documentation into the EHR with a healthcare scribe
- Review all labs within 48 hours of receipt
- Regularly update policy manual for staff to study
- Meet regularly with staff to improve and update manual
- Review protection plan every 6 months

II. Professional

- Review the Nevada PMP database prior to initiating controlled substances and review regularly for misuse
- Document a clear treatment plan with indications, goals, and duration of therapy
- Only prescribe and treat within my specialty and scope of practice
- Check state regulatory board's website quarterly for updates
- Annual CMEs in medical specialty (25 hours) and Bioidentical Hormone Replacement Therapy
- Use Two factor authentication method for approval of controlled substances
- Review PBI Proper Prescribing course slides and notes every 6 months
- Patient records show indications for all medications prescribed
- Always prescribe the lowest controlled substance dosage likely to be effective and the smallest appropriate quantity
- Always document adequate patient information to ensure subsequent physicians can provide care
- Never treat self, family, friends, or staff with controlled substances
- On every professional form or application, answer every question honestly and accurately
- No controlled substances prescriptions for people on alcohol

III. Personal

- Date night with wife once a week
- Weight training three times a week for 30-45 minutes
- Cardio (HIIT) training two-three times a week for 45 minutes to 1 hour
- Get 7 hours of sleep a night
- Build boundaries between myself and staff/patients regarding personal information
- Do not work after 6 pm in order to have quality family time
- Take two vacations annually with family and one personal annual retreat to reset, reflect, and regenerate
- Get annual check ups with a Primary Care Physician
- Continue bi-weekly volunteering with Life Outreach Church Center food distribution

Orlandis Lamar WELLS

License Number:
10558

License Type:
Medical Doctor

License Status:
Active-Probation

Initial License Date:
Jul-07-2003

Expiration Date:
Jun-30-2027

Public Address:
2637 W. Horizon Ridge Parkway, Suite 130

Public City:
Henderson

Public State:
Nevada

Public ZIP Code:
89052

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Obstetrics / Gynecology

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
Louisiana State University / New Orleans, LA	Medical Doctor Degree	N/A	May-15-1999

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
Louisiana State Univ Medical Ctr / New Orleans, LA	Internship	Obstetrics/Gynecology	Jul-01-1999	Jun-30-2000

Summary	Attachments
SETTLEMENT AGREEMENT AND ORDER Case No. 23-28073-1 and 23-28073-2 June 7, 2024 On June 7, 2024, the Nevada State Board of Medical Examiners (Board) accepted and approved a Settlement Agreement which allowed for an order to be entered finding that Dr. Wells violated NRS 630.301(4), as set forth in Counts I-IV, NRS 630.3062(1)(a), as set forth in Counts X-XIII, NRS 630.306(1)(b)(2), as set forth in Counts XVIII-XXI, and NRS 630.306(1)(g), as set forth in Counts XXVII-XXX of the Complaint in Case No. 23-28073-1, and NRS 630.301(4), as set forth in Counts I, V, IX and XIII, and NRS 630.306(1)(c), as set forth in Counts IV, VIII, XII and XVI of the Complaint in Case No. 23-28073-2, and ordered the following: Dr. Wells' license to practice medicine in the State of Nevada be revoked, with the revocation stayed, and his license placed on probation for a period of 24 months, subject to various terms and conditions, including the following: that Dr. Wells receive a public reprimand; pay a fine in the amount of $25,000; enroll in and complete the PROBE Ethics and Boundaries Program; complete 22 hours of Continuing Medical Education (CME), in addition to his statutory CME requirements for licensure before he applies for a license to prescribe controlled substances from the Nevada State Board of Pharmacy; and reimburse the Board's fees and costs incurred in the investigation and prosecution of the case. During the probationary period, Dr. Wells agrees not to reapply for a license to prescribe controlled substances from the Nevada State Board of Pharmacy for at least 1 year from the date of the Board's acceptance, adoption and approval of the Agreement and not until he successfully completes the 22 hours of CME and the PROBE Program. Dr. Wells shall not request early release from probation until he successfully completes the 22 hours of CME. During the probationary period, Dr. Wells may not supervise any physician assistants or collaborate with any advanced practice registered nurses. Within 14 days from the Board's acceptance, adoption and approval of the Agreement, Dr. Wells shall terminate any current supervising agreements with physician assistants and any current	Settlement Agreement and Order - 23-28073-1 & 2 Wells.pdf (/rest/public/data/downloadannotation/index.php?id=6691b2934d8f50473ebe7e54&entity=$2y$10$grKNeg3vysBpVGxvWnt/LuoFC2oTMVIMBZHAVW4rNLwb.u5/8kmqu)

Summary	Attachments
collaboration agreements with advanced practice registered nurses. The remaining counts of the Complaints were dismissed with prejudice.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Supervisor To

Licensee	Relationship	Date of Association
Valerie MADDOCKS	Primary Supervisor	Nov-18-2003
Dithra COTTON-LEWIS	Primary Supervisor	Jun-24-2019

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Olivia Mora

From: Pharmacy Licensing
Sent: Tuesday, January 13, 2026 8:39 AM
To: Olivia Mora
Subject: FW: Orlandis Wells MD
Attachments: Compliance Closure Letter Wells.pdf; WELLS, Orlandis, M.D. - Order Modifying Settlement Agreement.pdf

Olivia,

Please add these documents to the application for Orlandis Wells and add to the March agenda (appearance).

Kind Regards,

Mark Sedar
COO
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: ORLANDIS WELLS [redacted]
Sent: Monday, December 29, 2025 12:58 PM
To: Pharmacy Licensing <Pharmacylicensing@pharmacy.nv.gov>
Subject: Orlandis Wells MD

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

re: License # CS 36042

My name is Orlandis Wells and I am writing to up date my application that was submitted in November of 2025. There has been an update to my status with the medical board that I would like attached to my application that will be considered at the January 2026 meeting. My status has been updated from Active- Probation to Active with no restrictions.

Humbly submitted

Orlandis Wells MD

NEVADA STATE BOARD OF MEDICAL EXAMINERS
9600 Gateway Drive
Reno, NV 89521

Nick M. Spirtos, M.D., F.A.C.O.G.
Board President

Edward O. Cousineau, J.D.
Executive Director

December 29, 2025

Orlandis Wells, M.D.
[redacted]

Re: Compliance 23-28073-1 & 23-28073-2

Dear Dr. Wells:

This correspondence is to inform you that by your completion of the conditions set forth in the Settlement Agreement of June 7, 2024, the Investigative Committee of the Nevada State Board of Medical Examiners is satisfied. As you have fulfilled the terms of the Settlement Agreement, your Compliance file with the Nevada State Board of Medical Examiners has been closed.

Thank you for your cooperation on this matter. If you have any questions or if I may be of further assistance, please do not hesitate to contact me at (775) 324-9377.

Respectfully,

Johnna S. LaRue, CMBI
Deputy Chief of Investigations/Compliance Officer
Nevada State Board of Medical Examiners

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

BEFORE THE BOARD OF MEDICAL EXAMINERS
OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **ORLANDIS LAMAR WELLS, M.D.,** **Respondent.**	**Case Nos. 23-28073-1** **23-28073-2**

FILED
DEC 23 2025
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

ORDER MODIFYING SETTLEMENT AGREEMENT

Orlandis Lamar Wells, M.D. (Dr. Wells), License No. 10558, personally appeared in Las Vegas, Nevada, before the Nevada State Board of Medical Examiners (Board) at its regularly scheduled meeting on December 12, 2025, requesting that the Board remove the probationary condition on his license as outlined in the Settlement Agreement and Order (SAO), filed in this matter on June 7, 2024. Board members Nick M. Spirtos, M.D., F.A.C.O.G, President, Bret W. Frey, M.D., Vice President, Ms. Maggie Arias-Petrel, Secretary-Treasurer, Joseph Olivarez, P.A.-C, Jason B. Farnsworth, RRT, MBA, Hugh L. Bassewitz, M.D., FAAOS, Apeksha Desai, M.D., MBA, and Ms. Kathleen A. Conoboy, were present.

After considering Dr. Well's request, and his compliance with the remaining terms of the SAO, and good cause appearing, the Board enters the following Order:

IT IS HEREBY ORDERED that:

1. The probationary status on Dr. Well's license is hereby removed.

DATED this 23rd day of December, 2025.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
NICK M. SPIRTOS, M.D., F.A.C.O.G.
President of the Board

14

15

15A

Proposed Regulation of the Nevada State Board of Pharmacy

March 5, 2026

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 453.221; NRS 639.070

A REGULATION relating to controlled substances adding N-Pyrrolidino Metonitazene and N-Pyrrolidino Protonitazene to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

NAC 453.510 is hereby amended to read as follows:

1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alpha' -methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-phenylbutanamide);

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-

acetylmethadol, levomethadyl acetate or “LAAM”);

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethdol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Beta-methylacetyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)acetamide);

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

*2',5'-dimethoxyfentanyl (*N *-(1-(2,5 dimethoxyphenethyl)piperidin-4-yl)* N*-phenylpropionamide);*

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambuten;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

3-furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-3-carboxamide);

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Isovaleryl fentanyl (3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Isotonitazene;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Meta -fluorofentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Meta-fluorofuranyl fentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Meta -fluoroisobutyryl fentanyl (N-(3-fluorophenyl)- N-(1-phenethylpiperidin-4-yl) isobutyramide);

Methoxyacetyl fentanyl;

Methyl acetyl fentanyl;

2-Methyl-AP-237 (some trade or other names: 1-(2-methyl-4-(3- phenyl-2-propen-1-yl)-1-piperazinyl)-1-butanone; 2-MAP);

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

N-pyrrolidino metonitazene (some trade or other names: metonitazepyne or 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzo[d]imidazole, 2-hydroxy-1,2,3-propanetricarboxylate)

N-pyrrolidino protonitazene (some trade or other names: protonitazepyne or 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzo[d]imidazole)

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Ortho-chlorofentanyl (N-(2-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Ortho-fluorofuranyl fentanyl (N-(2-fluorophenyl)- N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Ortho-methylcyclopropyl fentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

Para chlorofentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-fluoro valeryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-methoxyfuranyl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para-methylcyclopropyl fentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Tetrahydrothiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrothiophene-2-carboxamide);

Tianeptine;

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

ADB–BUTINACA (some trade or other names: N -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1 H -indazole-3-carboxamide

ADB-4en-PINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide)

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazlo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Alpha -PiHP (some trade or other names: 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)

Bromazolam (some trade or other name: 8-bromo-1-methyl-6-phenyl H[1,2,4]triazolo[4,3a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

~~3~~-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

CUMYL-PEGACLONE (some trade or other names: SGT-151; 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one; 2,5-dihydro-2-(1-methyl-1-phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one)

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepine-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-

methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N- o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy- N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4- ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

4F-MDMB-BUTICA (some trade or other names: 4F-MDMB-BICA; Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(4-fluorobutyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, methyl)

5F-EDMB-PICA (some trade or other names: 5F-EDMB-2201; Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(5-fluoropentyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, ethyl ester)

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin- 2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018

indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

MDMB-4en-PINACA (some trade or other names: Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-

1H-indazole-3-carboxamido)butanoate)

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)

3–MMC (some trade or other names: 3-methylmethcathinone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one)

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

MMB-FUBICA ester (some trade or other names: Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate; N-[[1-[(4-fluorophenyl)methyl]-1H-indol-3-yl]carbonyl]-L-valine, methyl ester

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7- nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro- 2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.$1^{3,7}$]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin- 2-

one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine;

TFMPP).

 For the purposes of this subsection, “isomer” includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha- pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha- pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1- one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha- aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethylβ-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

Dipentylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2 (dimethylamino)pentan-1-one and N,N -dimethylpentylone)N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3- benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Ethylphenidate (some trade or other names: ethyl 2-phenyl-2-(piperidin-2-yl)acetate);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-

fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4- FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1- one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)- 2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N Methylcathinone,cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-

benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α- methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

➥ is not a controlled substance.

securities-offerings, and considered comments received at that time.

By the Commission.

Dated: January 7, 2026.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2026–00315 Filed 1–9–26; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1337]

Schedules of Controlled Substances: Placement of N-Pyrrolidino Metonitazene and N-Pyrrolidino Protonitazene in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration is permanently placing 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino metonitazene or metonitazepyne) and 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino protonitazene or protonitazepyne), including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, in schedule I under the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1961 Single Convention on Narcotic Drugs. This action imposes permanent regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with or possess), or handle *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene.

DATES: Effective February 11, 2026.

ADDRESSES: 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 (Single Convention), as amended by the 1972 Protocol. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations, the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the Controlled Substances Act (CSA), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970,'' the Attorney General must issue an order controlling such drug under the schedule she deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration.[1]

Background

On November 21, 2024, the Director-General of the World Health Organization recommended to the Secretary-General that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene be placed in Schedule I of the Single Convention, as these substances have pharmacological effects similar to other opioid drugs that are controlled in Schedule I of the Single Convention. On June 9, 2025, the Secretariat of the United Nations informed the United States government, by letter, that the Commission voted to place *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in Schedule I of the Single Convention during its 68th session on March 12, 2025 (CND Mar 68/2 and 68/1).

On August 15, 2025, DEA issued a temporary scheduling order, placing *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene temporarily in schedule I of the CSA.[2] That order for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene (codified at 21 CFR 1308.11(h)(77) and (78)) was based on the Administrator's finding that the temporary scheduling of these substances was necessary to avoid an imminent hazard to public safety.[3]

N-Pyrrolidino Metonitazene and N-Pyrrolidino Protonitazene

Benzimidazole-opioids, commonly referred to as ''nitazenes,'' emerged on the recreational drug market in 2019. This class of substances shares a similar pharmacological profile with fentanyl, morphine, and other mu-opioid receptor agonists. In 2023, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene emerged on the illicit opioid drug market. The abuse of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene has been associated with adverse events to include their identification in toxicology cases in the United States. Several substances belonging to the benzimidazole-opioid drug class have been controlled in the United States, and as a class of drug in China, Canada, and the United Kingdom.

Law enforcement reports demonstrate that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are being illicitly distributed and abused. According to the National Forensic Laboratory Information System (NFLIS-Drug)[4] database, which collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories, there have been 284 reports for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene between January 2022 and August 2025 (query date: August 13, 2025). Specifically, there have been 253 encounters of *N*-pyrrolidino protonitazene from 22 States and 31 encounters of *N*-pyrrolidino metonitazene from 10 States. Benzimidazole-opioids have been identified in counterfeit prescription tablets in the United States. A report from the Expert Committee on Drug Dependence Critical Review on *N*-pyrrolidino protonitazene indicate this

[1] 28 CFR 0.100.

[2] *Schedules of Controlled Substances: Temporary Placement of N-pyrrolidino metonitazene and N-pyrrolidino protonitazene in Schedule I*, 90 FR 39314 (August 15, 2025).

[3] *Id.*

[4] NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1 million distinct annual federal, state, and local drug analysis cases. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data are not direct evidence of abuse, these can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330, 77332 (Dec. 12, 2011).

substance has been sold online as ''China White'' heroin.[5]

N-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have no currently accepted medical use in treatment in the United States. The Department of Health and Human Services (HHS) advised DEA, by letter dated June 11, 2025, that based on a review by the Food and Drug Administration (FDA), there were no investigational new drug applications (IND) or approved new drug applications (NDA) for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in the United States. Since this letter, HHS has not advised DEA of any new IND or NDA for these substances. Because *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are not formulated or available for clinical use as approved medicinal products, all current use of these substances by individuals is based on their own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs.

Consistent with 21 U.S.C. 811(d)(1), DEA concludes that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have no currently accepted medical use in treatment in the United States[6] and are most appropriately placed permanently in schedule I of the CSA, the same schedule in which they temporarily reside. Because control is required under the Single Convention, DEA will not be initiating regular rulemaking proceedings to permanently schedule *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene pursuant to 21 U.S.C.811(a).

Conclusion

In order to meet the United States' obligation under the Single Convention and because *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have no currently accepted medical use in treatment in the United States, the Administrator has determined that *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, and salts are possible within the specific existence of such isomers, esters, ethers, and salts are possible within the specific chemical designation, should be placed permanently in schedule I of the CSA.

Requirements for Handling

As discussed above, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene have been temporarily controlled in schedule I of the CSA since August 15, 2025. Upon the effective date of this final order, *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene will be permanently subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement in research or conduct of instructional activities with, and possession of, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks. N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security. N*-Pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71 through 1301.76. Non-practitioners handling *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must comply with the screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

5. *Quota.* Generally, only registered manufacturers are permitted to manufacture *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene) on hand every two years pursuant to 21 U.S.C. 827 and 958(e) and in accordance

[5] 47th Expert Committee on Drug Dependence Critical Review on *N*-pyrrolidino protonitazene and *N*-pyrrolidino metonitazene. 14–18 October 2024.

[6] There is no evidence suggesting that *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene have a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *See Marijuana Scheduling Petition; Denial of Petition; Remand,* 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA applied the traditional five-part test and concluded the test was not satisfied. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care providers operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this scheduling order, there is no evidence that health care providers have widespread experience with medical use of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene or that the use of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied. By letter dated June 11, 2025, DEA has been advised by HHS that there are currently no approved new drug applications or investigational new drug applications for *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene. Additionally, HHS communicated no objections to the temporary placement of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene into schedule I of the CSA.

with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene must continue to comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene must continue to comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving *N*-pyrrolidino metonitazene or *N*-pyrrolidino protonitazene not authorized by, or in violation of the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review) and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review). DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulations, or E.O. 14294, Fighting Overcriminalization in Federal Regulations. This action makes no change in the status quo, as *N*-pyrrolidino metonitazene and *N*-pyrrolidino protonitazene are already listed as schedule I controlled substances.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of E.O. 13132. This action does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States' obligations under international treaties, conventions, or protocols.[7] If control is required pursuant to such international treaty, convention, or protocol, the Attorney General, as delegated to the Administrator, must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, and ''without regard to'' the findings and rulemaking procedures otherwise required for scheduling actions in 21 U.S.C. 811(a) and (b). *Id.*

In accordance with 21 U.S.C. 811(d)(1), scheduling actions for drugs that are required to be controlled by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, shall be issued by order, as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a). Therefore, DEA believes that the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[8] Also, this action does not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this action does require compliance with the following existing Office of Management and Budget (OMB) collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.)* that this final rule would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This order is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, DEA is submitting reports under the CRA to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

[7] 21 U.S.C. 811(d)(1).

[8] 44 U.S.C. 3501–3521.

■ a. Redesignate paragraphs (b)(79) through (119) as paragraphs (b)(81) through (121);
■ b. Add new paragraphs (b)(79) and (80); and
■ c. Remove and reserve paragraphs (h)(77) and (78).

The additions to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

* * * * * * *	
(79) 2-(4-methoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (Other names: *N*-pyrrolidino metonitazene; metonitazepyne)	9762
(80) 5-nitro-2-(4-propoxybenzyl)-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole (other names: *N*-pyrrolidino protonitazene; protonitazepyne)	9763
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Signing Authority

This document of the Drug Enforcement Administration was signed on January 5, 2025, by Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–00362 Filed 1–9–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2023–0590]

2023 Quarterly Listings; Fourth Quarter; Safety Zones, Security Zones, and Special Local Regulations

AGENCY: Coast Guard, DHS.

ACTION: Notification of expired temporary rules issued.

SUMMARY: This document provides notification of substantive rules issued by the Coast Guard that were made temporarily effective but expired before they could be published in the **Federal Register**. This document lists temporary safety zones, security zones, and special local regulations, all of limited duration and for which timely publication in the **Federal Register** was not possible. This document also announces notifications of enforcement for existing reoccurring regulations that we issued but were unable to be published before the enforcement period ended.

DATES: This document lists temporary Coast Guard rules and notifications of enforcement that became effective, primarily between October 2023 and December 2023, and expired before they could be published in the **Federal Register**.

ADDRESSES: Temporary rules listed in this document may be viewed online, under their respective docket numbers, at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this document contact Ambar Ali, Office of Regulations and Administrative Law, email *HQS-SMB-CG-LRA-Admin@uscg.mil,* telephone (202) 372–3862.

SUPPLEMENTARY INFORMATION: Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. *Safety zones* may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits, or it may be described as a zone around a vessel in motion. *Security zones* limit access to prevent injury or damage to vessels, ports, or waterfront facilities. *Special local regulations* are issued to enhance the safety of participants and spectators at regattas and other marine events.

Timely publication of these rules in the **Federal Register** may be precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, often informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels enforcing the restrictions imposed by the rule. Timely publication of notifications of enforcement of reoccurring regulations may be precluded when the event occurs with short notice or other agency procedural restraints.

Because **Federal Register** publication was not possible before the end of the effective period, mariners would have been notified of the contents of these safety zones, security zones, special local regulations, regulated navigation areas or drawbridge operation regulations by Coast Guard officials prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary safety zones, security zones, special local regulations, regulated navigation areas and drawbridge operation regulations. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if sufficient time is available to do so before they are placed in effect or terminated. In some of our reoccurring regulations, we say we will publish a notice of enforcement as one of the means of notifying the public. We use this notification to announce those notifications of enforcement that we issued and will post them to their dockets.

The following unpublished rules were placed in effect temporarily during the period between October 2023 and December 2023. To view copies of these rules, visit *www.regulations.gov* and search by the docket number indicated in the following table.

16

16A

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R107-25

December 15, 2025

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: § 1, NRS 453.146 and 639.070.

A REGULATION relating to controlled substances; revising the list of substances contained in schedule I; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act. (NRS 453.146) Existing regulations set forth the drugs and substances that are enumerated in schedule I. (NAC 453.510) This regulation revises the list of drugs and substances contained in schedule I to include Dipentylone and certain fentanyl-related substances.

Section 1. NAC 453.510 is hereby amended to read as follows:

453.510 1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-acetylmethadol, levomethadyl acetate or "LAAM");

Alphameprodine;

Alphamethadol;

Alpha'-methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethadol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Beta-methylacetyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)acetamide);

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

2',5'-dimethoxyfentanyl (N-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-N-phenylpropionamide);

Dimethylthiambutene;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

3-Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-3-carboxamide);

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Isotonitazene;

Isovaleryl fentanyl (3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Meta-fluorofentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Meta-fluorofuranyl fentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Meta-fluoroisobutyryl fentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl) isobutyramide);

Methoxyacetyl fentanyl;

Methyl acetyl fentanyl;

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Ortho-chlorofentanyl (N-(2-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Ortho-fluorofuranyl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Ortho-methylcyclopropyl fentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

Para-chlorofentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-fluoro valeryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-methoxyfuranyl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para-methylcyclopropyl fentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Tetrahydrothiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrothiophene-2-carboxamide);

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

Tianeptine;

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the

existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

ADB-4en-PINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide);

ADB-BUTINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1H-indazole-3-carboxamide;

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazolo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Alpha-PiHP (some trade or other names: 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one);

Bromazolam (some trade or other names: 8-bromo-1-methyl-6-phenyl-4H[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

CUMYL-PEGACLONE (some trade or other names: SGT-151; 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one; 2,5-dihydro-2-(1-methyl-1-phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N-o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-

NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy-N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4-ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

5F-EDMB-PICA (some trade or other names: 5F-EDMB-2201; Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(5-fluoropentyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, ethyl ester);

4F-MDMB-BUTICA (some trade or other names: 4F-MDMB-BICA; Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(4-fluorobutyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, methyl);

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4h-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin-2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

MDMB-4en-PINACA (some trade or other names: Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate);

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone);

3-MMC (some trade or other names: 3-methylmethcathinone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one);

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

MMB-FUBICA ester (some trade or other names: Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate; N-[[1-[(4-fluorophenyl)methyl]-1H-indol-3-yl]carbonyl]-L-valine, methyl ester);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin-2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzo[f]isochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as *Datura*, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha-pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha-pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha-aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethyl-β-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

Dipentylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2 (dimethylamino)pentan-1-one and N,N-dimethylpentylone);

N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4-FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1-one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)-2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N-Methylcathinone, cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α-methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

➥ is not a controlled substance.

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop December 4, 2025

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 453.221; NRS 639.070

A REGULATION relating to controlled substances adding dipentylone and seven fentanyl related substances to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

NAC 453.510 is hereby amended to read as follows:

1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alpha' -methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-phenylbutanamide);

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-

acetylmethadol, levomethadyl acetate or “LAAM”);

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethdol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Beta-methylacetyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)acetamide);

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

DRAFT

Cyclopentylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

*2',5'-dimethoxyfentanyl (*N *-(1-(2,5 dimethoxyphenethyl)piperidin-4-yl)* N*-phenylpropionamide);*

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambuten;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

DRAFT

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

3-furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-3-carboxamide);

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Isovaleryl fentanyl (3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Isotonitazene;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Meta -fluorofentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Meta-fluorofuranyl fentanyl (N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Meta -fluoroisobutyryl fentanyl (N-(3-fluorophenyl)- N-(1-phenethylpiperidin-4-yl) isobutyramide);

Methoxyacetyl fentanyl;

Methyl acetyl fentanyl;

2-Methyl-AP-237 (some trade or other names: 1-(2-methyl-4-(3- phenyl-2-propen-1-yl)-1-piperazinyl)-1-butanone; 2-MAP);

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

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Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Ortho-chlorofentanyl (N-(2-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Ortho-fluorofuranyl fentanyl (N-(2-fluorophenyl)- N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Ortho-methylcyclopropyl fentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

Para chlorofentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-fluoro valeryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-

yl)butyramide);

Para-methoxyfuranyl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para-methylcyclopropyl fentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Tetrahydrothiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrothiophene-2-carboxamide);

Tianeptine;

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

DRAFT

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

DRAFT

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

ADB–BUTINACA (some trade or other names: N -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1 H -indazole-3-carboxamide

ADB-4en-PINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide)

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazlo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Alpha -PiHP (some trade or other names: 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)

Bromazolam (some trade or other name: 8-bromo-1-methyl-6-phenyl H[1,2,4]triazolo[4,3a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

~~3~~-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

CUMYL-PEGACLONE (some trade or other names: SGT-151; 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one; 2,5-dihydro-2-(1-methyl-1-phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one)

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepine-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N- o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy- N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4- ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

4F-MDMB-BUTICA (some trade or other names: 4F-MDMB-BICA; Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(4-fluorobutyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, methyl)

5F-EDMB-PICA (some trade or other names: 5F-EDMB-2201; Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(5-fluoropentyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, ethyl ester)

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin- 2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

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[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

MDMB-4en-PINACA (some trade or other names: Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate)

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)

3–MMC (some trade or other names: 3-methylmethcathinone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one)

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-

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200);

MMB-FUBICA ester (some trade or other names: Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate; N-[[1-[(4-fluorophenyl)methyl]-1H-indol-3-yl]carbonyl]-L-valine, methyl ester

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7- nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro- 2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.$1^{3,7}$]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin- 2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-

benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora*

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williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

 For the purposes of this subsection, “isomer” includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha- pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha- pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1- one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha- aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethylβ-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

Dipentylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2 (dimethylamino)pentan-1-one and N,N -dimethylpentylone)N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3- benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Ethylphenidate (some trade or other names: ethyl 2-phenyl-2-(piperidin-2-yl)acetate);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4- FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1- one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-

methylcathinone, 1-(2-fluorophenyl)- 2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N Methylcathinone,cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4'-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-

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one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α- methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances,

derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

➥ is not a controlled substance.

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Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative Update

March 2026 - Temporary License since last Board Meeting

Pharmacist Name	Pharmacist License #
Judy Le	24937
Alexander Zerai	24938
Michelle Douglass	24686
Trang Phan	24960
Maryazucena Cutright	24959
Sandy Mathurin	24979
Tyler Hussey	24977
Todd Wise	24949

Business Name	License #	City, State
Gifthealth Pharmacy AZ	PH04785	Mesa, AZ

March 2026 – NV Business Address Change Only

Application Received	Business Name	License Number	New Location	City, State and Zip
1-26-2026	Vesper Specialty Pharmacy	PH03671	3329 S Eastern Ave	Las Vegas, NV 89169

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 –sent revised version to Dave/Yenh	12/10/24	1/16/25 – This public hearing was withdrawn from the agenda and will be heard at a future BM. 4/17/25 – To be heard at a future BM.		
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24	7/21/25 – Sent to Dave/Yenh for review.	10/28/25	12/4/25	1/21/26	

Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.	12/5/24	12/9/24	R203-24	9/19/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25	1/21/26	
Amendment to the Nevada Administrative Code ("NAC") 639.742. The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.	12/5/24 – Waiting for the federal reg to pass. The Board would like to see at a future meeting.							
A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/5/24	12/9/24	R204-24	7/23/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25	1/21/26	

Amendment to Nevada Administrative Code NAC 454. The proposed amendment revises the ability of an advanced emergency medical technicians to possess and administer dangerous drugs upon the order of a practitioner in a license hospital when practicing under their scope of practice as determined by the State of Nevada Health Department.	4/17/25	4/28/25	R004-25	7/22/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25 Note: Agenda item was "A REGULATION relating to the possession and administration of dangerous drugs by an advanced emergency medical technician or paramedic."	1/21/26	
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment specifies the requirements for pharmacies and practitioners to be authorized to engage in the sterile or nonsterile compounding of drug products.	7/17/25 – Need updated language from Dave to send to LCB for R Number.							

A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.	9/4/25 – Tabled and work with Homeopathic Board. 12/4/25	12/9/25	R106-25	1/21/26 – Sent to Dave/Yenh for review		4/16/26		
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish standards for licensees relating to staffing, supervision, duties of a pharmacy, duties of a pharmacist and requirements related to the timing of dispensing prescription drugs and devices	9/4/25 – Tabled and make modifications to language. 10/16/25 – Approved with amendments	10/22/25	R072-25					
A REGULATION relating to controlled substances adding dipentylone and seven fentanyl related substances to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/4/25	12/9/25	R107-25	12/17/25 – Sent to Dave/Yenh for review	1/28/26	3/5/26		

Amendment to Chapter 639 of the Nevada Administrative Code. The proposed amendments reduce the minimum age to register to become a pharmaceutical technician in training along with modify certain requirements to become a pharmaceutical technician in training.	1/15/26	1/20/26	R010-26	2/11/26				
Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding N-pyrrolidino metonitazene and N-pyrrolidino protonitazene to the controlled substances listed in Schedule I.	3/5/26							

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 7**
  - **Other: 1**

- **Citation & Fine –**
  - **Unlicensed Practice: 6**
  - **Misfill: 9**
  - **Other: 7**

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